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Dockets Management Branch
Division of Management System and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, (HFA-305)
Room 1061
Rockville, Maryland 20852

Docket No. 00D-0053

Dear Sir or Madame:

Boston Scientific Corporation (BSC) appreciates the opportunity to comment on the draft guidance documents regarding the reprocessing and reuse of single-use devices issued by the Food and Drug Administration (FDA) on February 8, 2000.[1] The Association of Disposable Device Manufacturers (ADDM), a trade association of which BSC is a member, is separately submitting detailed comments regarding the draft "Guidance for Enforcement Priorities for Single Use-Devices Reprocessed by Third Parties and Hospitals," as well as the Review Prioritization Scheme (RPS) that is set out

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[1] FDA, Guidance for Industry and for FDA Staff: Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (Draft Guidance) (Feb. 8, 2000); FDA, Guidance for Industry and FDA Reviewers: Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (Draft Guidance) (Feb. 8, 2000) (hereinafter RPS Guidance). The notice of availability of these documents for public comment was published in the Federal Register on February 11, 2000. Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme; and Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Availability, 65 Fed. Reg. 7027 (Feb. 11, 2000).

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in the draft guidance titled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme." BSC is submitting these comments regarding the application of the RPS to BSC's devices.

I. Gastroenterology-Urology Biopsy Instrument (21 C.F.R. § 876.1075)

BSC manufactures various single-use biopsy forceps.[2] Pursuant to the regulation regarding gastroenterology-urology biopsy instruments, BSC's non-thermal biopsy forceps are Class I devices that have been exempted from the premarket notification procedures and BSC's thermal biopsy forceps are Class II devices that have not been exempted from the premarket notification procedures.[3] Using the RPS flowcharts, devices in this category are high risk.

A. Infection Risk

1. Is the single-use biopsy forceps a non-critical device?

No. BSC's biopsy forceps are not non-critical devices. According to the Spaulding criteria as defined in the RPS Guidance, a non-critical device is one that "is intended to make topical contact and not penetrate intact skin."[4] Biopsy forceps penetrate the mucous membranes during use and are therefore not non-critical devices.

2. Does postmarket information suggest that using the reprocessed single-use biopsy forceps may present an increased risk of infection

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2 The "List of Frequently Reprocessed SUDs" in the RPS Guidance lists "non-electric biopsy forceps," 21 C.F.R. § 876.1075, as Class II, non-exempt devices that present a high risk when reprocessed. RPS Guidance, Appendix 2, at 28. The regulation actually classifies non-electric biopsy forceps as Class I devices that are exempt from the premarket notification procedures. 21 C.F.R. § 876.1075 (b)(2) Thus, BSC's non-thermal biopsy forceps are Class I, exempt devices and BSC's thermal biopsy forceps are Class II, non-exempt devices. The other regulations listed for biopsy forceps do not appear to apply to BSC's biopsy forceps. BSC agrees with FDA's determination that the overall risk level of biopsy forceps after reprocessing is high.

3 21 C.F.R. § 876.1075.

4 RPS Guidance at 5.

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when compared to the use of a single-use biopsy forceps that has not been reprocessed?

Yes. BSC is aware of postmarket information that demonstrates an increased risk of infection for reprocessed single-use biopsy forceps.

BSC has performed several studies of reprocessed single-use biopsy forceps.[5] In the first study, BSC examined the sterility of four commercially reprocessed biopsy forceps and found bioburden (aerobic and fungal) and microbial ID of colony growth in three of the four devices. This contamination of the tested units demonstrates that they were not suitable to be used on new patients even though it was claimed that the units had been sterilized with ethylene oxide (ETO) and ready for patient use.

In the second study, BSC examined nine reprocessed biopsy forceps obtained from hospital shelves. Of the four devices that were tested for sterility, two failed when subjected to the attached protocol.[6] In the third study, BSC examined eighteen commercially reprocessed biopsy forceps obtained from hospital shelves. Of the fourteen devices tested for sterility, nine failed, and of the four devices subjected to light microscopy, scanning electron microscopy, and photoelectron spectroscopy, one failed all three tests. In the fourth study, BSC examined seventeen commercially reprocessed biopsy forceps obtained from hospital shelves. Of the nine devices tested for sterility, all nine devices failed, and of the eight devices subjected to light microscopy, scanning electron microscopy, and photoelectron spectroscopy, one device failed light microscopy and scanning electron microscopy and four devices failed scanning electron microscopy. In the fifth study, BSC examined 20 commercially reprocessed biopsy forceps obtained from hospital shelves. Of the ten devices examined for the presence of bioburden, five devices failed, and of the ten devices tested for sterility, four devices failed.

BSC also conducted a study of 21 biopsy forceps that had been reprocessed and labeled as sterile that was published in Infection Control Today.[7] This study revealed that four of the five devices tested for sterility failed and that two of the three devices

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5 These studies were submitted to FDA on September 17, 1999.

6 BSC Protocol. All of these studies utilized the attached protocol. (See Attachment 1)

7 Cogdill, C.P. and Quaglia, L. Reuse of Single-Use-Only Biopsy Forceps: How Safe and Effective Is It?, Infection Control Today (Feb. 1998). (See Attachment 2)

analyzed destructively for contamination were found to be contaminated by a substance identified by pathological examination as blood.[8] Summarizing these results, of the 56 devices tested for sterility or the presence of bioburden, 36 devices failed. Moreover, of the 15 devices subjected to other physical testing, eight failed.

Information regarding reusable biopsy forceps also demonstrates that reprocessing biopsy forceps presents a risk of infection. According to a study regarding risks associated with reuse of reusable biopsy forceps, "[i]t is recognized that there is a population of patients harboring unidentified infectious diseases. The transmission of infectious agents such as *Salmonella* species, *Pseudomonas aeruginosa*, *Helicobacter pylori*, *Stronglyoides stercoralis* and both the hepatitis B and C viruses has been reported to occur as a result of GI endoscopy [footnotes omitted]."[9] Moreover, according to an editorial in Gastrointestinal Endoscopy, "[m]ost important, with regard to safety, there is no doubt that biopsy forceps can transmit disease. Both hepatitis B and C transmission have been linked to biopsy forceps, as have been bacterial infections including *Salmonella newport* and *Helicobacter pylori*. In the latter study, *H pylori* DNA detected by nested polymerase chain reaction was experimentally transferred to non infected tissue by biopsy forceps [footnotes omitted]."[10]

While this information is sufficient under the RPS to demonstrate that biopsy forceps present a high risk of infection after reprocessing, BSC will answer the rest of the questions in the flowchart to further demonstrate that reprocessed biopsy forceps are high risk devices.

3. Does the single-use biopsy forceps include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes. The single-use biopsy forceps have features that would impede thorough cleaning and adequate sterilization. In general, the devices are comprised of steel wires surrounded with a lubricious coated plastic sheath that is placed inside a tightly wound metal coil that is encased in a polymer sheath. The wires are attached to the jaw of the

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8 Id.

9 Rizzo, J. et al. A performance, safety and cost comparison of reusable and disposable endoscopic biopsy forceps: a prospective randomized trial, Gastrointestinal Endoscopy, 51(3), at 260 (2000).

10 Gordon, S.J. Reusable versus disposable forceps: the dilemma of cost and safety, Gastrointestinal Endoscopy, 51(3), at 364 (2000).

forceps at the distal end, and there is a plastic handle control and spool assembly by which the device is controlled at the proximal end. The outer sheaths covering these devices create long (240 cm) and very narrow lumens with outside diameters as small as 2.2 mm.[11] The coil that surrounds the coated plastic sheath creates many interstices in which debris accumulates during use. Because the lumen of the biopsy forceps is open only at the distal end, flushing is not a viable option. In fact, attempts to clean the biopsy forceps by flushing have been shown to spread contaminants out further in the instrument.[12]

The metal coil surrounding the steel wires is attached to the jaw assembly by crimping the proximal end of the jaw assembly. Debris may accumulate at this site. These devices also have very small interlocking parts and crevices in the hinge by which the jaw mechanism of the biopsy forceps is attached to the wire assembly. Each of these features would impede thorough cleaning of the device. As the studies discussed above confirm, a reprocessed single-use biopsy forceps is thus likely to contain residual tissue. This would render ETO sterilization ineffective because of ETO's inability to penetrate biological tissue. However, because the handle and spool assembly as well as the inner plastic sheath that surround the steel wires are plastic and cannot be sterilized using steam, reprocessors are currently using ineffective ETO sterilization.

FDA recently issued a Warning Letter to Vanguard Medical Concepts, Inc. (Vanguard) regarding problems with Vanguard's practices of reprocessing biopsy forceps. Among the problems noted by FDA was the fact that there was "no demonstration that the [ETO] gas will reach all areas within narrow lumens and long tubes."[13]

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11 An article published by ECRI in a special report regarding reuse of single-use devices discusses the sorts of devices that would be candidates for reprocessing and states that "[d]evices with long and/or small-diameter lumens, with rough or textured surfaces and deep groves or crevices, that are composed of porous materials and constructed with hinges or other features that may interfere with cleaning should probably not be considered." ECRI, Evaluating the Feasibility of Reusing a Single-Use Device, Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions, at 55 (1996). (See Attachment 3)

12 Roth, K. et al. Quality Assurance on Reprocessing Accessories for Flexible Endoscopes – Just How Clean are Cleaned Instruments Really?, Central Service 7(2), at 7 (1999). (See Attachment 4)

13 FDA, Warning Letter from Tolen to Masek, Jr. of Vanguard, at 5 (Oct. 14, 1999).

With respect to biopsy forceps as well as single-use devices generally, it is important to note that the answers to questions regarding design features that might impede cleaning and sterilization can really only be answered by the manufacturers themselves. Reprocessors will often not know about the specific coatings, assemblies, materials, etc. that might present obstacles to reprocessing the devices.[14]

4. Does a reusable device exist that has an equivalent design and the same intended use as the single-use biopsy forceps?

No. The design of BSC's single-use biopsy forceps is not equivalent to the design of reusable biopsy forceps. The handle and spool assembly of reusable biopsy forceps are made of polysulphone, a substance that is designed to withstand steam sterilization, while single-use biopsy forceps use a less expensive plastic that is not designed to withstand steam sterilization. The steel wires in the single-use biopsy forceps are surrounded with a plastic sheath and coating which will not withstand steam sterilization.[15] The reusable biopsy forceps do not contain the coating or the plastic sheath. In addition, the metal coil to jaw assembly of the reusable biopsy forceps is a welded design,[16] while the metal coil to jaw assembly of the single-use device is a crimp design.[17] The welded design is sturdier than the crimp design which might give way after reuse. The reusable biopsy forceps incorporate a riveted link assembly to attach the wires to the jaw,[18] while the single-use biopsy forceps utilize the "Z-bend" wire formation to attach the wire to the jaw.[19] The rivet assembly is sturdier than the wire formation which is reliable for a single use but not for multiple uses. The jaws of the reusable biopsy forceps are machined from stainless steel, which is durable enough for autoclaving; the jaws of the single-use biopsy forceps are cast from a more malleable proprietary material.

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14 This is also true with respect to design features that might be damaged or altered by reprocessing in such a way that performance of the device might be adversely affected.

15 See Attachment 5.

16 See Attachment 6.

17 See Attachment 7.

18 See Attachment 8.

19 See Attachment 9.

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Moreover, the jaws of the reusable biopsy forceps have cutting edges without teeth,[20] while the single-use biopsy forceps have micromesh teeth that may be dulled or bent through use or reprocessing and were not designed to withstand repeated cleaning.[21]

5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the single-use biopsy forceps has been adequately cleaned and disinfected/sterilized?

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the single-use biopsy forceps have been adequately cleaned and sterilized. Moreover, BSC has not developed any performance tests that may be used to determine if any single-use biopsy forceps can be adequately cleaned and sterilized for multiple uses.

6. Is this a semi-critical device?

No. According to the Spaulding criteria as defined in the RPS Guidance, these biopsy forceps are critical devices because, similar to a needle or scalpel, they break intact mucous membranes and come in contact with sterile tissue during normal operation. Moreover, in guidelines published by the Society of Gastroenterology Nurses and Associates (SGNA), biopsy forceps have been classified as critical devices.[22]

Thus, application of FDA's risk infection flowchart demonstrates that BSC's single-use biopsy forceps present a high risk of infection after reprocessing. This finding is sufficient to render this device "high risk" under the RPS Guidance. Review of the second flowchart confirms that these devices are high risk..

B. Inadequate Performance Risk

1. Does postmarket information suggest that using the reprocessed single-use biopsy forceps may present an increased risk of injury when

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20 See Attachment 8.

21 See Attachment 9.

22 SGNA, Recommended Guidelines for Infection Control in Gastrointestinal Endoscopy Settings at Series 4 (1990).

compared to the use of a single-use biopsy forceps that has not been reprocessed?

Yes. BSC is aware of postmarket information that demonstrates increased risk of injury for reprocessed biopsy forceps. In one of the studies submitted to FDA on September 17, 1999, BSC examined five biopsy forceps for functional performance and observed three device failures. In the study conducted by BSC that was published in Infection Control Today, approximately 40% of the thirteen devices tested for functional performance would have been rejected according to BSC's standards for new devices.[23]

While this information is sufficient to demonstrate that biopsy forceps present a high risk of inadequate performance after reprocessing, BSC will answer the rest of the questions in the flowchart to further demonstrate that biopsy forceps are high risk devices.

2. Could failure of the device cause death, serious injury or permanent impairment?

Yes. Biopsy forceps are traditionally used to obtain tissue for the diagnoses of cancer, *H Pylori*, Chrons and Colitis, Tuberculosis and other diseases of the pulmonary and digestive systems. Failure to obtain adequate uncrushed tissue specimens could result in a misdiagnosis for a patient that might ultimately result in cancer or other life-threatening diseases that could go undiagnosed. Moreover, the distal assembly attachment is not designed, manufactured and tested to withstand the sterilization process. Therefore, increased risk of leaving metal components from the distal assembly potentially exists if single-use devices are reprocessed. Furthermore, if the needle of the forceps should protrude or become disengaged from the forcep, perforation may occur.

3. Does the single-use biopsy forceps contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

Yes. The biopsy forceps contain materials, coatings, and/or components that could be damaged or altered by reprocessing in such a way that the performance of the devices may be adversely affected. First, the sharpness of the teeth may be affected by

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[23] Cogdill, C.P. and Quaglia, L. Reuse of Single-Use-Only Biopsy Forceps: How Safe and Effective Is It?, Infection Control Today (Feb. 1998). (See Attachment 2)

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use and reprocessing, causing problems with the collection of the samples during the procedure. Second, the sharpness of the needle used to hold the tissue in place while the jaws cut the sample may be affected by use and reprocessing so that the needle might not be able to correctly hold the tissue in place for the collection of the sample. Third, if the inner plastic sheath melts on to the wires which it encases, the ability of the jaws to open and close could be affected. Fourth, the "Z-bend" method of attaching the wires to the jaw mechanism could give way after reuse and reprocessing.

4. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the single-use biopsy forceps has been altered due to reprocessing and use?

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the performance of the single-use biopsy forceps has been altered due to reprocessing and use. Moreover, BSC has not developed any performance tests that may be used to determine if the performance of the single-use biopsy forceps has been altered by reprocessing and subsequent use.

5. Can visual inspection determine if performance has been affected?

No. Visual inspection may not reveal whether the performance of the biopsy forceps has been affected by reprocessing. Visual inspection cannot determine whether the inner plastic sheath has melted onto the wires. Visual inspection cannot determine whether the sharpness of the teeth or the needle has been affected. Visual inspection cannot determine whether the "Z-bend" attachment will give way during the next use of the device.

Thus, application of FDA's risk of inadequate performance flowchart demonstrates that BSC's biopsy forceps present a high risk of inadequate performance after reprocessing.

II. Ureteral Stone Dislodgers (21 C.F.R. § 876.4680)

BSC manufactures various single-use stone retrieval baskets and urological grasping forceps.[24] Ureteral stone dislodgers are Class II devices that have been

[24] The "List of Frequently Reprocessed SUDs" in the RPS Guidance lists "extraction balloons/baskets," 21 C.F.R. § 876.1500, as high risk devices. RPS Guidance,

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exempted from the premarket notification procedures.[25] However, under the RPS Guidance, these devices are high risk according to both flowcharts.

A. Infection Risk

1. Is the single-use stone retrieval basket or urological grasping forceps a non-critical device?

No. BSC's stone retrieval baskets and urological grasping in forceps are not non-critical devices. According to the Spaulding criteria as defined by the RPS Guidance, a non-critical device is one that "is intended to make topical contact and not penetrate intact skin."[26] Depending on the nature of the procedure in which a stone retrieval basket or grasping forceps is used, the device is either a semi-critical device or a critical device. When a device in this category is introduced into the patient via an endoscope inserted into the natural opening of the ureter, the device is a semi-critical device because it is intended to contact intact mucous membranes. When a device in this category is used in a percutaneous procedure utilizing a trocar instead of the natural opening, the device is a critical device because it is intended to contact tissue that is normally sterile. In neither situation are stone retrieval baskets or grasping forceps non-critical devices that are intended to make topical contact and not penetrate intact skin.

2. Does postmarket information suggest that using the reprocessed single-use stone retrieval basket or urological grasping forceps may present an increased risk of infection when compared to the use of a single-use stone retrieval basket or urological grasping forceps that has not been reprocessed?

Appendix 2, at 28. BSC's stone retrieval baskets and urological grasping forceps are covered by the regulation for ureteral stone dislodgers, 21 C.F.R. § 876.4680, and not by 21 C.F.R. § 876.1500. BSC is providing comments pertaining to these devices because it is unclear whether FDA intended the extraction balloon/basket risk category analysis to apply to BSC's stone retrieval baskets and grasping forceps. If FDA did intend for the extraction balloon/basket category to include stone retrieval baskets and urological grasping forceps, BSC agrees with FDA that the overall risk level of these devices after reprocessing is high.

25 21 C.F.R. § 876.4680.

26 RPS Guidance at 5.

No. BSC is not aware of any postmarket information regarding risk of infection for reprocessed stone retrieval baskets or urological grasping forceps. However, based on their design features, these reprocessed devices do present greater safety risks.

3. Does the single-use stone retrieval basket or urological grasping forceps include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes. Both the stone retrieval baskets and the grasping forceps have features that would impede thorough cleaning and adequate sterilization. In general, the devices are comprised of an intricate wire assembly almost entirely encased in a polymer sheath with an exposed wire basket or grasping mechanism at the distal end and a plastic handle control at the proximal end. The sheaths covering these devices create very narrow lumens with diameters as small as 1.9 FR that are only open at the distal end. The wire assembly that runs through the length of the sheath is often braided, creating many interstices in which debris may accumulate during use. In addition, to allow the device to be as small as possible, there is a low clearance between the wire and the inner surface of the sheath surrounding the wire. This low clearance will prevent cleaning devices and/or fluid from easily passing into the narrow lumen. Moreover, because the lumens of the baskets and grasping forceps are open only at the distal end, flushing is not a viable option. These devices also have interlocking parts at the site where the stone retrieval basket cage or grasping mechanism is attached to the wire assembly. BSC has observed debris caught in this junction in used devices that have been returned to BSC. The plastic handles for these devices also have moving levers which are used to open and close the baskets and grasping forceps; these handles have many hard-to-reach spaces which may harbor debris from prior use. Each of these features would impede thorough cleaning of the device. A reprocessed single-use basket or grasping forceps is thus likely to contain residual tissue and could not be effectively sterilized with ETO because of ETO's inability to penetrate biological tissue. However, because the handles for both the baskets and the grasping forceps are plastic and cannot be sterilized using steam, reprocessors are currently using ineffective ETO sterilization.[27]

4. Does a reusable device exist that has an equivalent design and the same intended use as the single-use stone retrieval basket or urological grasping forceps?

No. While reusable stone retrieval baskets and grasping forceps do exist, the designs of BSC's single-use grasping forceps are not equivalent to the designs of the

27 FDA, Warning Letter from Tolen to Masek, Jr. of Vanguard, at 5 (Oct. 14, 1999).

reusable devices. For example, BSC is aware of a reusable handle that is intended to be used with several different disposable baskets. The reusable handle is made from aluminum rather than plastic to facilitate sterilization. The reusable grasping forceps are larger than BSC's single-use grasping forceps, have fewer small parts, and do not utilize plastic handles. BSC is also aware of reusable stainless steel baskets that manufacturers sell with their endoscopes. These devices, like the other reusable devices, are larger and sturdier than BSC's single-use devices and do not have plastic handles that limit the type of sterilization that may be performed on the devices. The single-use design of BSC's basket and grasping forceps permits utilization of different components which result in a smaller device because they do not require components that will withstand the rigors of cleaning, sterilization, and subsequent reuse.

5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the single-use stone retrieval basket or urological grasping forceps has been adequately cleaned and disinfected/sterilized?

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the stone retrieval basket or urological grasping forceps have been adequately cleaned and sterilized. BSC is aware of a guidance document titled "510(k) Checklist for Mechanical Lithotripters and Stone Dislodgers Used in Gastroenterology and Urology."[28] This document, however, does not specify any performance standards relating to cleaning and sterilizing single-use devices. Moreover, BSC has not developed any performance tests that may be used to determine if any single-use baskets or grasping forceps can be adequately cleaned and sterilized for multiple uses.

6. Is this a semi-critical device?

No. As discussed in section II.A.1 above, these stone retrieval baskets and grasping forceps are critical devices when used in percutaneous procedures utilizing trocars because they would come in contact with tissue that is normally sterile.

Thus, application of FDA's risk infection flowchart demonstrates that BSC's stone retrieval baskets and urological grasping forceps present a high risk of infection after reprocessing. This finding is sufficient to render this device "high risk" under the RPS.

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28 FDA, 510(k) Checklist for Mechanical Lithotripters and Stone Dislodgers used in Gastroenterology and Urology (Nov. 1, 1994).

Review of the second flowchart also demonstrates that single-use stone retrieval baskets and urological grasping forceps are high risk devices when reprocessed.

B. Inadequate Performance Risk

1. Does postmarket information suggest that using the reprocessed single-use stone retrieval basket or urological grasping forceps may present an increased risk of injury when compared to the use of a single-use stone retrieval basket or urological grasping forceps that has not been reprocessed?

No. BSC is not aware of any postmarket information regarding risk of injury for reprocessed stone retrieval baskets and urological grasping forceps. However, as discussed below, these devices do present a greater risk of injury when reprocessed.

2. Could failure of the device cause death, serious injury or permanent impairment?

Yes. Failure of either a stone retrieval basket or urological grasping forceps could cause serious injury in several different ways. If one of the wires comprising the stone retrieval basket breaks during use, the broken wire could snag the ureter. This may require open surgery to repair the ureter. If the wires comprising the basket become less flexible, the basket might not be able to reopen when necessary. This could cause the basket to become stuck in the ureter if the stone that is being removed is too large to be extracted while in the basket, and would require intervention to release the stone and remove the basket. With respect to grasping forceps, a hook from the forceps which had become brittle during reprocessing could sever off from the device and lodge in the ureter. This would also require surgical intervention.

3. Does the single-use stone retrieval basket or urological grasping forceps contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

Yes. Both the stone retrieval baskets and the urological grasping forceps contain materials, coatings, and/or components that could be damaged or altered by reprocessing in such a way that the performance of the devices may be adversely affected. First, the devices bear a proprietary coating on the inner lumen that facilitates lubricity between the polymer sheath and the basket assembly or the grasping forceps to allow the devices to open and close easily. As the devices are used, this coating wears off. Moreover, the cleaning and sterilization procedures required for reprocessing would also cause the proprietary coating to wear off.

Second, because the handles of the devices are made out of plastic, the devices are not steam sterilizable. Therefore, BSC uses ETO to sterilize the new devices after manufacture. However, repeated use of ETO or gamma radiation could have a negative effect on other materials used in the basket and grasping forceps. For example, the cyanoacrylate adhesive BSC uses to connect the wires together or attach the basket to the wire assembly could undergo expedited aging when exposed to further ETO or gamma radiation. The cyanoacrylate adhesive also becomes more brittle with exposure to humidity. If the adhesive fails, the retrieval basket may be left in the body, requiring intervention to remove the basket.

Third, these devices are made with thin wires. Reprocessing these devices may cause kinking of the wires which could render the devices inoperable. The distal end of certain of the devices is designed to be very delicate so that it will be more flexible during use. However, this flexibility also makes it more likely that the device will kink, particularly with increased handling. Reprocessing necessarily involves additional handling of the devices. Such kinking weakens the wires of the devices and could render the devices inoperable.

Fourth, some retrieval baskets and grasping forceps are accompanied by introducers to help the physicians feed the devices into the endoscopes and reduce kinking. Because the introducers are relatively small pieces that are not attached to the baskets and grasping forceps, the introducers might become separated from the baskets and grasping forceps, either before being sent to be reprocessed or during the reprocessing procedures. As a result, the devices that would be returned to physicians for reuse might be lacking introducers.

4. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the single-use stone retrieval basket or urological grasping forceps has been altered due to reprocessing and use?

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the performance of the single-use stone retrieval baskets or urological grasping forceps has been altered due to reprocessing and use. As mentioned in the discussion of performance standards with respect to risk of infection, BSC is aware of the 510(k) checklist for mechanical lithotripters and stone dislodgers.[29] While this document applies to both single-use devices and reusable devices, this checklist does not provide any performance standards relating to reprocessing stone retrieval baskets or grasping forceps that were not designed for reuse.[30] Moreover, BSC has not developed any performance tests that may be used to determine if the performance of the single-use basket or grasping forceps has been altered by reprocessing and subsequent use.

5. Can visual inspection determine if performance has been affected?

No. Visual inspection may not reveal whether the performance of the stone retrieval baskets or the grasping forceps has been affected by reprocessing. Visual inspection cannot determine whether the proprietary coating on the lumen of the polymer sheath remains. Similarly, failure of the cyanoacrylate adhesive will not be visible after reprocessing. Furthermore, neither broken wires inside the opaque polymer sheath nor wires that are fatigued and might break upon use will be visible upon inspection after reprocessing.

Thus, application of FDA's risk of inadequate performance flowchart demonstrates that BSC's stone retrieval baskets and urological grasping forceps present a high risk of inadequate performance after reprocessing.

III. Urological Catheter and Accessories (21 C.F.R. § 876.5130)

BSC manufactures various urological guidewires intended to provide a foundation for diagnostic and therapeutic catheters.[31] Pursuant to the regulation regarding urological

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29 510(k) Checklist at 4-5.

30 The fact that a checklist exists that provides guidance for the content of a 510(k) submission for stone dislodgers should not be enough to downgrade the devices from high risk to moderate risk. It would be an odd result if the risk level of reprocessing a single-use device was lowered simply because a guidance document addresses standards for new devices generally and also states that if the device is reusable, it must be able to withstand multiple cleanings. This guidance document provides no insight into what would be acceptable standards for reprocessing a single-use device, and therefore cannot be used to justify a lower level of risk.

31 The "List of Frequently Reprocessed SUDs" in the RPS Guidance describes "urethral catheters" as Class II, non-exempt devices that present a moderate level

catheters and accessories, these devices are Class I devices that have been exempted from the premarket notification procedures.[32] However, applying the RPS Guidance to these devices shows that they are high risk under both flowcharts.

A. Infection Risk

1. Is the single-use urological guidewire a non-critical device?

No. As with BSC's stone retrieval baskets and urological grasping forceps discussed in section II.A.1 above, urological guidewires are not non-critical devices according to the Spaulding criteria as defined in the RPS Guidance. Depending on the nature of the procedure in which a guidewire is used, the device will be considered either a semi-critical device or a critical device. When a device in this category is introduced into the patient via an endoscope inserted into the natural opening of the ureter, the device is a semi-critical device because it is intended to contact intact mucous membranes. When a device in this category is used in a percutaneous procedure utilizing

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of risk when reprocessed. RPS Guidance, Appendix 2, at 28. The list also describes "endoscopic guidewires" as Class II, non-exempt devices that present a low level of risk when reprocessed. Id. While BSC's urological guidewires fall within the regulation cited for urethral catheters, 21 C.F.R. § 876.5130, it is not clear whether the list's category of "urethral catheters" is meant to apply to BSC's urological guidewires because the characteristics of BSC's guidewires do not correspond to the accompanying information on the list. BSC's guidewires are not catheters and are Class I, exempt devices rather than Class II, non-exempt devices. BSC's urological guidewires are similarly not a perfect match for the endoscopic guidewires category. BSC's urological guidewires do not fall within the regulation cited for endoscopic guidewires, 21 C.F.R. § 876.1500, and, as with the urethral catheters, the description of the devices as Class II, non-exempt devices does not correspond to the actual classification for BSC's urological guidewires.

BSC is providing comments pertaining to its urological guidewires because it is unclear whether FDA intended either of the categories provided on the list to apply to BSC's urological guidewires. If FDA did intend for either the urethral catheter category or the endoscopic guidewire category to include urological guidewires, BSC disagrees with FDA's assessment that the overall risk level of these devices after reprocessing would be moderate for the urethral catheter category or low for the endoscopic guidewire category.

32 21 C.F.R. § 876.5130.

a trocar instead of the natural opening, the device is a critical device because it is intended to contact tissue that is normally sterile. In neither situation do urological guidewires qualify as non-critical devices.

2. Does postmarket information suggest that using the reprocessed single-use urological guidewire may present an increased risk of infection when compared to the use of a single-use urological guidewire that has not been reprocessed?

No. BSC is not aware of any postmarket information regarding risk of infection for reprocessed urological guidewires. However, as discussed below, the features of these products do present an increased risk of infection after reprocessing.

3. Does the single-use urological guidewire include features that could impede thorough cleaning and adequate sterilization/ disinfection?

Yes. BSC's urological guidewires have features that would impede thorough cleaning and adequate sterilization. In general, the devices are wires of varying size that are enclosed in various types of outer sheaths or jackets with various types of tip designs at the distal end of the devices. In some models, the guidewire is comprised of a wire running through the center of a tightly coiled flexible metal sheath. This outer sheath is like an accordion, and the space between the coils can increase or decrease depending on how the device in maneuvered. Both patient material and residuals from the cleaning process lodge in the coils. BSC's guidewires are also coated with a proprietary coating to facilitate lubricity. This coating is hydrophilic and apt to absorb body fluids during the procedures in which the guidewires are used and/or cleaning fluids during the cleaning process. Unless the coating is totally removed from the device, these patient and/or cleaning fluids may remain on the devices when used in subsequent patients.

4. Does a reusable device exist that has an equivalent design and the same intended use as the single-use urological guidewire?

No. BSC is not aware of any reusable urological guidewires.

5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the single-use urological guidewire has been adequately cleaned and disinfected/sterilized?

Boston Scientific

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the urological guidewires have been adequately cleaned and sterilized. Moreover, BSC has not developed any performance tests that may be used to determine if any single use guidewires can be adequately cleaned and sterilized for multiple uses.

6. Is this a semi-critical device?

No. As discussed in section III.A.1 above, these urological guidewires are critical devices when used in percutaneous procedures utilizing trocars because they would come in contact with tissue that is normally sterile.

Thus, application of FDA's flowchart regarding the risk of infection after reprocessing demonstrates that BSC's urological guidewires are high risk devices. While this finding is sufficient to render this device "high risk" under the RPS Guidance, the second flowchart corroborates that these are high risk devices.

B. Inadequate Performance Risk

1. Does postmarket information suggest that using the reprocessed single-use urological guidewire may present an increased risk of injury when compared to the use of a single-use urological guidewire that has not been reprocessed?

No. BSC is not aware of any postmarket information regarding risk of injury for reprocessed urological guidewires. However, as discussed below, these single-use devices do present a greater risk of injury when reprocessed.

2. Could failure of the device cause death, serious injury or permanent impairment?

Yes. Failure of a urological guidewire could cause serious injury in several different ways. If the guidewire is being used in a procedure to remove a stone and the guidewire breaks at a point distal to the stone, a secondary open surgical procedure to remove the wire may be required. Moreover, if the distal spring tip on the guidewire fails while inside the patient, severe ureteral trauma may result. Lastly, if a portion of the wire breaks off and is left in the urinary tract, it could be a catalyst for future stone formation that may eventually require treatment.

3. Does the single-use urological guidewire contain any materials, coatings or components that may be damaged or altered by a single use

or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

Yes. BSC's urological guidewires contain materials, coatings, and/or components that could be damaged or altered by reprocessing in such a way that the performance of the devices may be adversely affected. First, the guidewires bear a proprietary lubricant on the outside of the devices that facilitates movement through the endoscope that will wear off as the devices are used. Moreover, the cleaning and sterilizing procedures that would be used on the devices would also be likely to cause the proprietary coating to wear off. Second, the cyanoacrylate adhesive at the spring joint could weaken with use or degrade with age, causing the spring coil to detach from the core wire. Third, some guidewires contain a braised joint that could be affected by the harsh solvents that would likely be used to clean the devices. Fourth, some guidewires are accompanied by introducers to help the physicians feed the devices into the endoscopes without kinking. Certain guidewires, particularly the polytetrafluorethylene (teflon) version, are more likely to kink without the aid of an introducer. Because the introducers are relatively small pieces that are not attached to the guidewires, the introducers might become separated from the guidewires, either before being sent to be reprocessed or during the reprocessing procedures. As a result, the devices may be returned to physicians for reuse without introducers.

4. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the single-use urological guidewire has been altered due to reprocessing and use?

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the performance of the single-use urological guidewires has been altered due to reprocessing and use. Moreover, BSC has not developed any performance tests that may be used to determine if the performance of the single-use urological guidewires has been altered by reprocessing and subsequent use.

5. Can visual inspection determine if performance has been affected?

No. Visual inspection may not reveal whether the performance of the urological guidewires has been affected by reprocessing. Visual inspection cannot determine whether the proprietary coating on the outside device remains. Similarly, failure of the cyanoacrylate adhesive will not be visible after reprocessing. Furthermore, internal wires that are fatigued and might break upon use will not be visible upon inspection after reprocessing.

Thus, application of FDA's flowchart regarding the risk of inadequate performance after reprocessing demonstrates that BSC's urological guidewires are high risk devices.

IV. Electrode Recording Catheter or Electrode Recording Probe (21 C.F.R. § 870.1220)

BSC manufactures various electrophysiology catheters (EP catheters).[33] Pursuant to the regulation regarding electrode recording catheters, these devices are Class II devices that are not exempt from the premarket notification procedures.[34] The RPS flowcharts demonstrate that devices in this category are high risk.

A. Infection Risk

1. Is the EP catheter a non-critical device?

No. BSC's EP catheters are not non-critical devices. According to the Spaulding criteria as defined in the RPS Guidance, a non-critical device is one that "is intended to make topical contact and not penetrate intact skin."[35] EP catheters contact normally sterile tissue when they are used and are therefore not non-critical devices.

2. Does postmarket information suggest that using the reprocessed single-use EP catheter may present an increased risk of infection when compared to the use of a single-use EP catheter that has not been reprocessed?

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33 The "List of Frequently Reprocessed SUDs" in the RPS Guidance lists "electrophsyiology recording catheter" as a Class II, non-exempt device covered by the regulation at 21 C.F.R. § 870.1120 that presents a high risk when reprocessed. RPS Guidance, Appendix 2, at 27. BSC believes that this list intended to cite the regulation at 21 C.F.R. § 870.1220 since 21 C.F.R. § 870.1120 refers to blood pressure cuffs. BSC agrees with FDA's determination that the overall risk level of EP catheters after reprocessing is high.

34 21 C.F.R. § 870.1220.

35 RPS Guidance at 5.

Yes. BSC is aware of postmarket information that suggests that using reprocessed EP catheters presents an increased risk of infection. First, at an Association for the Advancement of Medical Instrumentation (AAMI)/FDA conference regarding reuse of single-use devices, Stanley Brown and Katharine Merritt of CDRH's Office of Science and Technology presented preliminary data from an FDA study of EP catheter reprocessing. In this study, FDA observed the leaking of patient fluid into the hollow chamber of reprocessed EP catheters that resulted in debris collecting in that space.[36] Dr. Brown stated that this discovery has led him to consider conducting formal leak testing on EP catheters.[37]

Second, an article from the Rocky Mountain News discussing the deaths of two patients on whom EP catheters had been used at University Hospital also suggests that using reprocessed catheters may present an increased risk of infection.[38] Both patients died from a reaction to endotoxin. While the article does not state that this University Hospital reprocesses EP catheters, and therefore does not conclude that the endotoxin made its way into the catheter lab through reprocessed devices, the article does note that traces of endotoxin were found in one of the flush baskets used to rinse catheters. This might suggest that the catheters in the lab were being reprocessed.

While this information is sufficient to demonstrate that EP catheters present a high risk of infection after reprocessing, BSC will answer the rest of the questions in the flowchart to further demonstrate that EP catheters are high risk devices.

3. Does the single-use EP catheter include features that could impede thorough cleaning and adequate sterilization/disinfection?

Yes. BSC's single-use EP catheters include many features that could impede thorough cleaning and sterilization. In general, these devices are comprised of hollow plastic tubing with electrodes mounted at the distal end of the tubing. BSC also manufactures a Constellation EP catheter that has a collapsible sphere with eight flexible

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36 AAMI/FDA, The Re-Use of Single-Use Devices: Practice, Patient Safety and Regulation, transcript at 67 (May 5, 1999).

37 Id. at 242.

38 Michael Romano, For Heart Patients, A Deadly Scare. Scores Undergo Routine Procedure Since Death Nov. 11, but Questions Linger in Catheter Lab Rocky Mountain News Archive (1995). (See Attachment 10)

ribs that each bear eight electrodes. Where the basket of the Constellation catheter meets the catheter shaft and at the distal hub that connects to each rib, there are many crevices where debris may accumulate. Crevices are also created at the catheter-electrode interface in both the Constellation and other EP catheters. In addition, the adhesive attaching the electrodes to the catheters can sometimes allow blood to enter the core of the catheter. Each of these features would impede thorough cleaning of the device. A reprocessed single-use EP catheter is thus likely to contain residual patient material and could not be effectively sterilized with ETO. However, because the plastic used in the catheters cannot withstand steam sterilization or gamma radiation, a reprocessor would likely resort to ineffective ETO sterilization.

4. Does a reusable device exist that has an equivalent design and the same intended use as the single-use EP catheter?

No. BSC is not aware of any reusable EP catheters.

5. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the single-use EP catheter has been adequately cleaned and disinfected/sterilized?

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the EP catheters have been adequately cleaned and sterilized. Moreover, BSC has not developed any performance tests that may be used to determine if any single-use EP catheters can be adequately cleaned and sterilized for multiple uses.

6. Is this a semi-critical device?

No. These EP catheters are critical devices because they break intact mucous membranes and come in contact with tissue that is normally sterile when introduced into the heart.

Thus, application of FDA's risk infection flowchart demonstrates that BSC's EP catheters present a high risk of infection after reprocessing. This finding renders this device "high risk" under the RPS Guidance. The second flowchart confirms this conclusion.

B. Inadequate Performance Risk

1. Does postmarket information suggest that using the reprocessed single-use EP catheter may present an increased risk of injury when compared to the use of a single-use EP catheter that has not been reprocessed?

Yes. BSC is aware of postmarket information that suggests that using reprocessed EP catheters presents an increased risk of injury when compared to the use of single-use EP catheters that have not been reprocessed. According to a MedWatch report submitted to FDA, a reprocessed catheter failed during use in a patient when a "[s]mall piece of metal electrode broke off while still in heart and lodged in the right atrium."[39] This incident demonstrates a new failure mode for EP catheters that has never been seen with a new catheter. While BSC is aware of incidents in which an entire electrode has disengaged from the catheter, this is the first report of a piece of electrode falling off the tip – that is, in this instance, metal sheared off of metal. This failure mode presents an increased risk of injury to patients over new devices because, while EP catheters are generally equipped with a safety wire to catch a disengaged electrode, no such safety mechanism exists for electrode pieces.

According to another MedWatch report submitted to FDA, a small section of the distal tip in close proximity to the electrode side of an EP catheter broke away. The fragment could not be located.[40] An examination of the device by BSC after the event revealed visual findings of corrosive failure and the presence of high levels of chlorine that could be due to the use of bleach. This suggests that the failure of this device might have resulted from materials used to reprocess the device.

While this information is sufficient to demonstrate that EP catheters present a high risk of inadequate performance after reprocessing, BSC will answer the rest of the questions in the flowchart to further demonstrate that EP catheters are high risk devices.

2. Could failure of the device cause death, serious injury or permanent impairment?

Yes. Failure of a single-use EP catheter could cause serious injury in several ways. If the electrodes are not flat against an EP catheter, blood clots may begin to form in that space which may result in emboli. If the adhesive used to attach the electrodes to

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[39] MedWatch Report, No. 1015923 (Mar. 8, 1999).

[40] MedWatch Report, Mfr. Report No. 6000087-1998-00002 (Apr. 17, 1998).

the catheter is missing, it may also cause an embolus. If the embolus occurs in the left chamber, it could cause a stroke to the brain or an infarction.

3. Does the single-use EP catheter contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?

Yes. The single-use EP catheters contain materials, coatings, and/or components that could be damaged or altered by reprocessing in such a way that the performance of the devices may be adversely affected. First, with respect to the Constellation catheter, there is a heparin coating that would be lost through use and a sterilization process. Second, the ribs of the Constellation catheter might fracture at the tip of the sphere due to stress after multiple cycles of opening and collapsing the sphere beyond its validated limits. Third, the metal from which the Constellation catheter ribs are constructed may corrode or become embrittled with exposure to any chlorinated solvent used to clean the device during reprocessing. Fourth, the adhesive used to attach the electrodes to an EP catheter might degrade during reprocessing, causing the electrodes to detach during a procedure or not lay flush against the catheter. This could also cause a biocompatibility problem since the materials inside the channel of the device are not demonstrated to be biocompatible because they are not intended to come in contact with the patient. Fifth, the bi-directional steerability of the catheters will diminish with use because there are a limited number of steering cycles that the catheter has before there is fatigue failure.

4. Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document (which includes specifications, test protocols and acceptance criteria) that may be used to determine if the performance of the single-use EP catheter has been altered due to reprocessing and use?

No. BSC is not aware of any recognized performance standards or any CDRH guidance documents that may be used to determine if the performance of the single-use EP catheter has been altered due to reprocessing and use. Moreover, BSC has not developed any performance tests that may be used to determine if the performance of the single-use EP catheter has been altered by reprocessing and subsequent use.

5. Can visual inspection determine if performance has been affected?

No. Visual inspection may not reveal whether performance of the EP catheter has been adversely affected due to reprocessing. Visual inspection will not reveal whether

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the heparin coating has been lost from the Constellation catheter or whether there is corrosion or embrittlement in the constellation catheter ribs. Visual inspection will also not reveal whether the steering will fail or there will be fatigue failure on the next use. Nor will visual inspection reveal whether there is a problem with the metal under the outer plastic coating.

Thus, application of FDA's risk of inadequate performance flowchart demonstrates that BSC's EP catheters present a high risk of inadequate performance after reprocessing.

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BSC appreciates the opportunity to comment on the application of the RPS to its single-use devices. Application of the risk of infection and risk of inadequate performance flowcharts to BSC's single-use biopsy forceps, stone retrieval baskets and urological grasping forceps, urological guidewires, and EP catheters demonstrates that each of these categories of devices present a high risk of infection and inadequate performance after reprocessing, and therefore should be placed in the high risk category.

Sincerely,

Kshitij Mohan

Kshitij Mohan, M.D.
Senior Vice President
Chief Technical Officer

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GROUP: **TEST PROTOCOL**	
DOCUMENT NO.:	REVISION NO.: A
INITIATED BY:	Page 1 of
TITLE: Sterility and Pyrogen Testing for Reprocessed Medical Devices From A Health Care Facility	

1.0 Purpose

This protocol provides the steps to be followed in order to evaluate sterility and the absence of pyrogens (LAL Test) for the products post reprocessing at a Health Care Institute. This testing will be performed using the following facility:

Laboratory to be Named by Sponsor

2.0 Reference Documents:

2.1 ISO 11737-1:1995 "*Sterilization of Medical Devices –Microbiological methods – Part 1: Estimation of the population of microorganisms on product*"
2.2 ISO 11737-2(in press) "*Sterilization of Medical Devices –Microbiological methods – Part 2: Tests of sterility performed in the validation of a sterilization process*"
2.3 *USP 23; The United States Pharmacopeial, <1211> Sterilization and Sterility Assurance of Compendial Articles,1995, pg1980.*
2.4 *Association for the Advancement of Medical Instrumentation (AAMI). Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers. AAMI TIR No. 12. Arlington (VA): AAMI; 1994.*

3.0 Scope:

Manufacturers are required to conduct very stringent testing processes for reusable products. They must meet FDA criteria that follow the Association for the Advancement of Medical Instrumentation (AAMI)[1] guidance document with four fundamental aspects of device design that manufacturers should consider when developing a medical device intended to be reused. These include physical, material, total system, and user-related design considerations. Good device design accounts for the environment in which the device will be used and the environment in which it will be reprocessed within the healthcare facility.

Cleaning and decontamination are recognized as the crucial first steps in any effective reprocessing protocol, and devices must be designed to be compatible with these protocols. The size, shape, and configuration of an instrument can significantly affect how adequately it can be cleaned. Fine surface crevices, porous materials, or other physical features that encourage the retention of microbes, toxic sterilants, cleaning solution residues, and physiological fluids or residues must be avoided. Biofilms that form on instrument surfaces contacting body fluids can be tenacious and require vigorous scrubbing to effectively remove. The design must also take into account variations in technique and skill of central

[1] Association for the Advancement of Medical Instrumentation (AAMI). Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: a guide for device manufacturers. AAMI TIR No. 12. Arlington (VA): AAMI; 1994.

sterile supply personnel, and any design that does not allow unobstructed access to surfaces for cleaning cannot be considered for a reusable medical device.

Adequate cleaning entails removal of visible and non-visible soil from body fluids, tissues, and other debris that remain following use of the device. All surfaces of the device, including channels and lumens that may have been in contact with the patient or physiologic fluids, must be accessible to ensure proper cleaning. If the product cannot be adequately cleaned, sterilization will not be reliable, and pyrogenic reactions may occur even if the device is sterile[2]. Moreover, if all potentially contaminated surfaces of a critical or semicritical device cannot be inspected for cleanliness after each use, then it should not be reused[3].

This study will evaluate the products which have been used and reprocessed by or for a Health Care institute per the manufacturers or reprocessors instructions. The reprocessed devices must meet the same sterility and non-pyrogenic state per the validated reprocessed instructions.

4.0 Equipment, Media and Reagents

Equipment

- 4.1 Face masks
- 4.2 Gloves, sterile surgeon's latex
- 4.3 Bunsen burner
- 4.4 Scissors
- 4.5 Forceps, serrated
- 4.6 Graduated cylinder, various sizes as needed, sterile
- 4.7 Pipets, various sizes as needed, sterile
- 4.8 Test tubes, various sizes as needed, sterile
- 4.9 Petri dishes, 100 mm x 15 mm, sterile
- 4.10 Incubator, 30-35°C
- 4.11 Colony Counter
- 4.12 Laminar Flow Biological Cabinet, Class 100
- 4.13 Standard Clean Room Garments, sterile

Culture Media and Reagents

- 4.14 Soybean Casein Digest Broth (SCDB), pH 7.3 ± 0.2
  - a. 1000 ml screw-cap containers
  - b. Terminally sterilize at 121°C, liquid cycle
- 4.15 Soybean Casein Digest Agar (SCDA), pH 7.3 ± 0.2
  - a. Screw-cap containers
  - b. Terminally sterilize at 121°C, liquid cycle
- 4.16 Disinfectant - Sodium hypochlorite, minimum 0.2% solution

[2] ECRI. Special Report: Reuse of Single-Use Medical Devices: Making Informed Decisions. Plymouth Meeting (PA):ECRI;1997.
[3] Joint Commission on Accreditation of Healthcare Organizations (JCAHO). 1996 accreditation manual for hospitals, section 2. Surveillance, prevention and control of infection (IC). Oakbrook Terrace (IL): JCAHO:453-66.

.0 Procedure:

Bioburden\Sterility test of Reprocessed clinical USED Biopsy Forceps units

4.17 The Lab will perform a Bioburden\Sterility testing at (30-35°C) on the 10 single pouched reprocessed USED biopsy forceps units.

4.18 Aseptically cut forceps into approximately 30 cm segments and put each device into sterile containers (containing a minimum of 500 mL of TSB).

4.19 Rotary shaker the containers (do not allow media to contact the lid of the container) for 15 minutes at approximately 150 rpm at room temperature.

4.20 Aseptically filter 50 mL onto a 0.45μ or smaller filter membranes. Following the filtration roll each membrane onto TSA or BAP plate for Bioburden testing (total aerobic microbial count).

4.21 Additionally, Plate duplicate one (1) mL aliquots and incorporate with molten, tempered TSA (pour plate method).

4.22 Incubate all plates for 72 hours at 30-35°C and then transfer the plates to room temperature (20-25°C) for an additional 4 days.

4.23 If any plates or broth are positive (microbial growth evident), Streak onto TSA for isolation. Identify all isolates to genus and species (for bacteria) or genus (for fungi).

Modified USP Sterility Testing (Thioglycollate Broth will not be used as per USP guidelines).

4.24 The Lab. will perform a 14 day USP Sterility test (20-25°C) on an additional 10 single pouched reprocessed USED biopsy forceps units.

4.25 Aseptically flush forceps with 30 ml of TSB (flushed SCDB will be captured in the 1000 ml sterility container) at the end of the flushing allow TSB to remain inside the forceps lumen. Aseptically put the device into sterile containers (containing 1000 ml of SCDB) ensuring that the device is fully immersed in the media. Repeat procedure for all remaining devices.

4.26 Incubate all SCDB broth cultures for 14 days at 20-25°C.

Bacterial Endotoxin (LAL) Testing

4.27 Perform a quantitative determination of pass/fail endotoxin limit on 5 units single-pouched, reprocessed biopsy forceps units.

4.28 The lumens of each biopsy forcep will be flushed with a portion of the 40 mL SWFI with the remaining volume added to cover the device. The devices will be pooled into one container for the extraction.

6.0 Acceptance Criteria

For these tests to be acceptable, there must be no units with positive microbial growth from both the 14 day USP sterility test and the bioburden\sterility test. The endotoxin level must be 0.5 EU/ml or less for the samples tested.

6.1 Report:

The final report will include individual reports for Bioburden\Sterility test results, Modified USP sterility test results and LAL results.

6.2 Records:

All raw data pertaining to this study and a copy of the final report will be retained in designated archive files.

6.3 Approval

SPONSOR:

NAME:________________________________ TELEPHONE:________________

TITLE:________________________________ FACSIMILE:________________

SIGNATURE:____________________________ DATE:_____________________

ViroMED Biosafety LABORATORIES

TEST REQUEST FORM

SHIP SAMPLES TO:
ViroMed Biosafety Laboratories
2540 Executive Drive
St. Paul, MN 55120
TOLL FREE 800.582.0077
FAX 612.563-3289

Photocopy and then complete this form to accompany a sample for testing. (Supply all appropriate information for optimum final reports.)
A signed protocol must be attached to this form for testing to be initiated.

CLIENT INFORMATION

CONTACT NAME	
COMPANY NAME	
ADDRESS	
CITY	STATE ZIP
PHONE	
FAX	

SAMPLE INFORMATION

SAMPLE NAME / DESCRIPTION	
SAMPLE ID NUMBERS (Batch, Lot, Load, Etc.)	
QUANTITY SENT	RETURN SAMPLES? *(Add'l fee applies)* ☐ YES ☐ NO
STERILIZATION / PROCESSING DATE	STERILIZATION METHOD *(If appl.)*

BILL TO (If different from above)

PURCHASE ORDER NUMBER
(Required)

TEST(S) REQUESTED:

☐ **Bioburden/Sterility**

TEST CODE	QTY	PRICE*	TEST DESCRIPTION
1606000		$40.00 each	Aerobic Bioburden
1227000		$8.50 each	USP Product Sterility

☐ **Modified USP Sterility Testing**

TEST CODE	QTY	PRICE*	TEST DESCRIPTION
1227000		$8.50 each	USP Product Sterility

☐ **Bacterial Endotoxin (LAL) Testing**

TEST CODE	QTY	PRICE*	TEST DESCRIPTION
130501		$80.00 each	Kinetic Chromogenic LAL Limit Test [Samples will be tested separately.]

* *Note: Pricing expires 08/01/2000*

COMMENTS FOR THE LAB:

NOTES FOR THE REPORT:

LAB USE ONLY

QTY REC'D________ DATE REC'D________ TECH________ ACC #________

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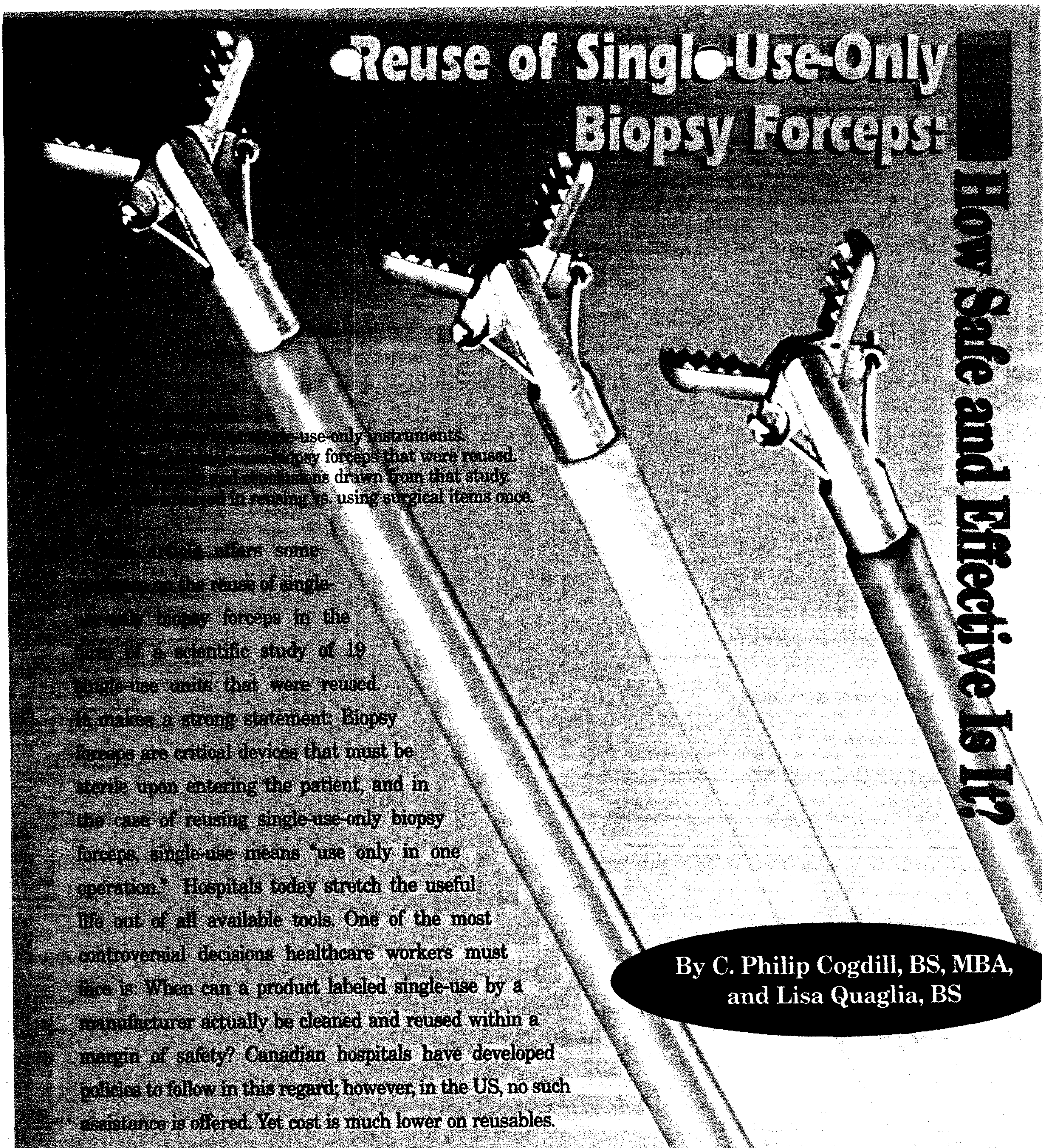
ENDOSCOPES
http://www.vpico.com/ict/

Reuse of Single-Use-Only Biopsy Forceps: How Safe and Effective Is It?

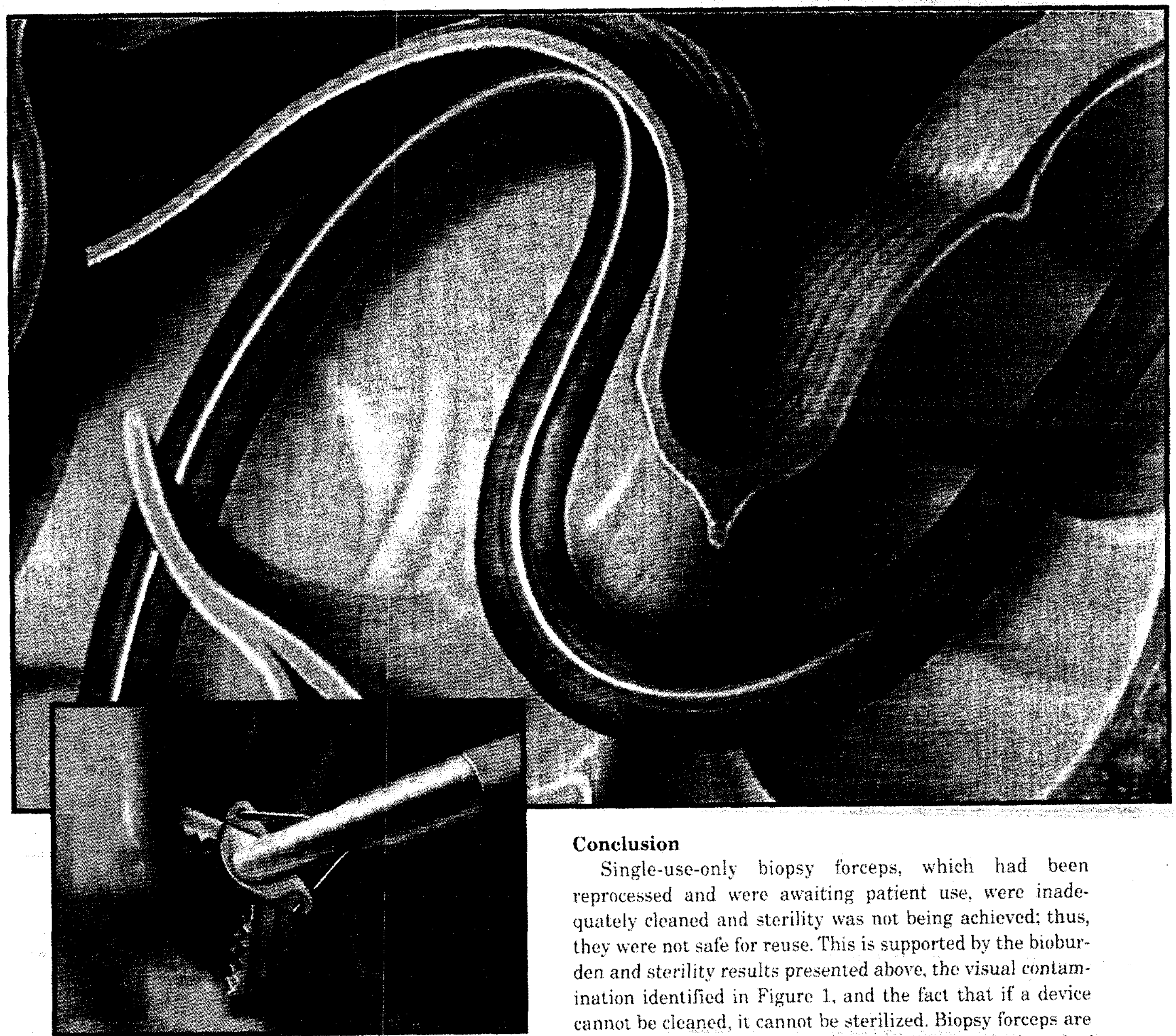


By C. Philip Cogdill, BS, MBA, and Lisa Quaglia, BS

[illegible] single-use-only instruments. [illegible] biopsy forceps that were reused. [illegible] and conclusions drawn from that study. [illegible] in reusing vs. using surgical items once.

[illegible] article offers some [illegible] the reuse of single-use-only biopsy forceps in the form of a scientific study of 19 single-use units that were reused. It makes a strong statement: Biopsy forceps are critical devices that must be sterile upon entering the patient, and in the case of reusing single-use-only biopsy forceps, single-use means "use only in one operation." Hospitals today stretch the useful life out of all available tools. One of the most controversial decisions healthcare workers must face is: When can a product labeled single-use by a manufacturer actually be cleaned and reused within a margin of safety? Canadian hospitals have developed policies to follow in this regard; however, in the US, no such assistance is offered. Yet cost is much lower on reusables.

In view of the controversy surrounding reprocessing of single-use biopsy forceps and the lack of data, we evaluated 19 Boston Scientific single-use biopsy forceps. These forceps had been reprocessed by a third-party reprocessor, labeled "sterile," and were in hospitals, awaiting use. The following observations and conclusions were made from the products tested: Sterility and bioburden tests were performed on five devices, four were found to be non-sterile (though labeled sterile), three of the four tested for bioburden were found to have microbial counts from 8 to 32 colony-forming units (cfu) per device. Nine devices were tested for performance and quality-assurance criteria, which included a visual, microscopic, and



in Figure 1) demonstrates that the design of single-use devices render the cleaning step inadequate. The remaining contamination and lack of sterility associated with reprocessed single-use biopsy forceps present an increased risk of cross-contamination from patient to patient, and no dollar value can be attached to patient safety.

Conclusion

Single-use-only biopsy forceps, which had been reprocessed and were awaiting patient use, were inadequately cleaned and sterility was not being achieved; thus, they were not safe for reuse. This is supported by the bioburden and sterility results presented above, the visual contamination identified in Figure 1, and the fact that if a device cannot be cleaned, it cannot be sterilized. Biopsy forceps are critical devices according to the Spaulding/CDC method of classification, and must be sterile upon entering the patient. Further examination must be done to determine functionality. The assumed financial benefits of reprocessing single-use biopsy forceps are unfounded and have not accounted for the risks of nosocomial infection, which are far greater than the perceived cost savings provided with the reprocessing of single-use biopsy forceps. ✦

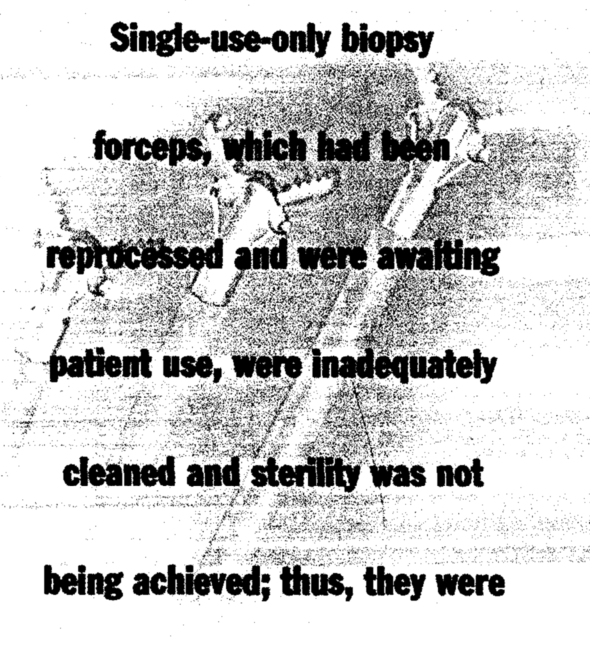
Table 3—Group C: Performance Testing

Test	1	2	3	4	5	6	7	8	9	10	11	12	13
Jacketed	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Kinks	1 Lg.	No	No	No	No	No	No	No	No	No	No	No	No
Feel Test	N/A	N/A	N/A	Pass	Nicks, scratches	Pass	Nicks	Nicks	Nicks	N/A	Pass	2 Perfs.	Pass
# Uses	3	1	3	1	2	1	1	1	1	2	Unk	Unk.	Unk.
Handle Pull	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Pull Test	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Loop Test	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Ring Gage	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Cutter Engage	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Rotation Test	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Comments		Gap in cutters	Sl. curve in coil		Sl. curve in coil	Scratches	Sl. curve in coil	Corrosion evident	Sl. curve in coil	Gap in gutters	Visible corrosion	Curve in coil, cutter tension	Chip on needle

supplied with an outside jacket. Only those biopsy forceps with the outside jacket were subjected to the "feel" test. Table 3 summarizes the performance and quality data for each device.

While many of the attributes of the established functional test criteria were passed by many devices, degradation of the physical properties in some of the devices was identified and is noted in Table 3. Of these units, approximately 40% of these devices would have been rejected by Boston Scientific/Microvasive™ standards. The majority of these devices have been used only once, with only two devices being used three times. Many facilities will reuse single-use biopsy forceps until they fail during a procedure, which could entail many more uses and increase procedure time while another device is obtained. As is shown in Table 3, many of the quality attributes have begun to degrade after the intended use. Further testing needs to be performed to determine the reliability effects of reprocessing these single-use devices.

Upon completion of the functional performance testing, destructive visual inspection was conducted. This inspection identified contamination on all reprocessed units that was not found on new unused biopsy forceps. A comparison of some of these results is identified in Figure 1.



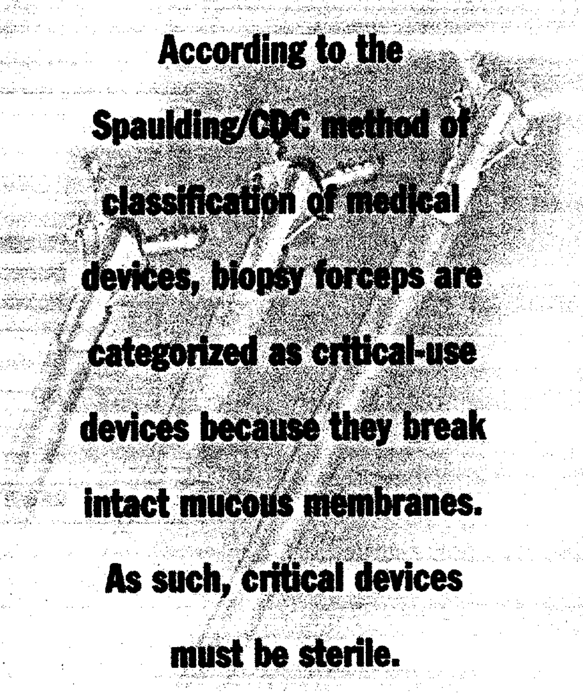
Single-use-only biopsy forceps, which had been reprocessed and were awaiting patient use, were inadequately cleaned and sterility was not being achieved; thus, they were not safe for reuse.

Cost Evaluation

Healthcare facilities determined to control costs may look at the reprocessing of single-use biopsy forceps. This is based on the assumption that reprocessed single-use biopsy forceps are equivalent in risk and performance to new, single-use biopsy forceps and the practice of reusing single-use forceps will reduce overall costs. However, when facilities consider the numerous factors required to implement the 12-step guidelines for reprocessing devices, the cost savings are minimal, if any. Another option, to avoid the implementation and operating costs of reprocessing, is to outsource the reprocessing of devices to a third-party reprocessor, which may charge a flat fee based on quantity, or may offer to reprocess single-use biopsy forceps at half the acquisition cost. With an average cost less than $40 for a biopsy forceps, the assumed savings is less than $20 per device. This savings does not take into consideration the cost of increased scope repair (which has been shown to be 253% higher with reusable devices than with single-use only), the increase in procedure time due to diminished performance and device failures, and most importantly, the increased risk of cross-contamination. The Society of GI Nurses and Assistants (SGNA) says that cleaning is a crucial step in reprocessing devices. Data presented in this study (*see photos* one pathological examination. These demonstrated that all had been unsatisfactorily cleaned, with tissue, blood and/or chemical residues remaining on the forceps.

Using the AAMI TIR 12 as a foundation for the acceptance criteria to evaluate the effectiveness of reprocessing, we found that all the devices did not meet the acceptance criteria. The reprocessing of single-use-only devices presents an increased health risk to the patient and a loss of device effectiveness.

According to the Spaulding/CDC method of classification of medical devices, biopsy forceps are categorized as critical-use devices because they break intact mucous membranes. As such, critical devices must be sterile. In response to the need for cost containment in the healthcare industry, many hospital facilities face the decision of reusing these single-use medical devices. The objectives of these studies were to determine whether reused, single-use biopsy forceps are safely and effectively being cleaned for reuse, as well as to determine performance and assess cost comparison. Measurable endpoints evaluated included bioburden, sterility, functionality, contamination identification, and actual costs.



According to the Spaulding/CDC method of classification of medical devices, biopsy forceps are categorized as critical-use devices because they break intact mucous membranes. As such, critical devices must be sterile.

Methods and Results

Three groups of testing on single-use biopsy forceps were performed: • bioburden/sterility, • pathological exam, and • functionality were performed. A total of 21 Microvasive™ single-use biopsy forceps were analyzed. All units had been reprocessed by a third-party reprocessor and were labeled as "sterile." All units were obtained from hospital standard inventory awaiting patient use.

In Group A, five Microvasive™ single-use biopsy forceps were sent to a contract laboratory for bioburden residue/sterility testing. Four of the five units tested were found to be non-sterile. Microbial growth was performed on colonies of similar morphology and was identified as staphylococcus and corynebacterium. Table 1 summarizes these results.

Group B consisted of three single-use biopsy forceps and was also sent out to a contract laboratory to be analyzed destructively for contamination. Several areas of visual contamination were found on two of the three units (*Table 2*). These were forwarded for pathological examination and identification. The results of pathologic exam identified this contamination to be blood. Several other contaminants present were not identified due to the timing of the study.

Cleaning is essential in reprocessing medical devices. The intricate design and lengthy catheter shaft of biopsy forceps, combined with the small ID, make it almost impossible to clean the device adequately for sterilization. Blood residuals left within the catheter shaft may make their way into another patient and cause further nosocomial infections, such as hepatitis.

Performance and visual testing performed in Group C consisted of 13 Microvasive™ single-use biopsy forceps. Some of these are

Table 1—Group A: Bioburden/Sterility Testing

Unit	Sterilization Method	Bioburden Detected	Type	Sterile
1	EtO	0 CFUs	N/A	Yes
2	EtO	12 CFUs	Aerobic	No
3	EtO	32 CFUs	Aerobic	No
4	EtO	8 CFUs	Aerobic	No
5	EtO	N/A*	N/A	No

*This unit was not analyzed for bioburden residues

Table 2—Group B: Pathologic Examination

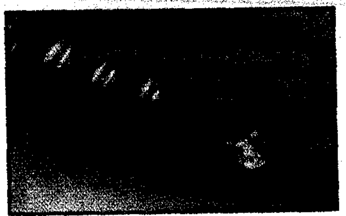
Unit	Contamination Found	Identified As
1	red/rust like substance	Blood

Figure 1: Data presented in study based on visual inspection demonstrates that the design of single-use devices render the cleaning step inadequate.

Reprocessed Units

Forceps coil connection with residual disinfectant and cleaning chemicals.

Forceps coil connection with blood and rust.

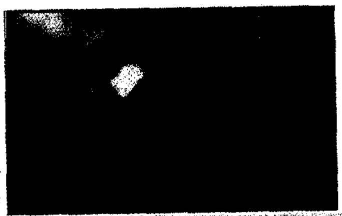


Debris on coil of forceps.

Forceps needle with clip debris.

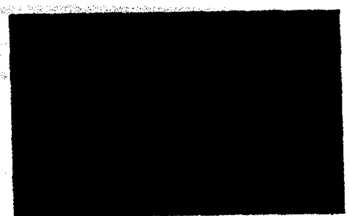
Blood and rust on coil of forceps.

Inside cup of jaw with rust and debris.



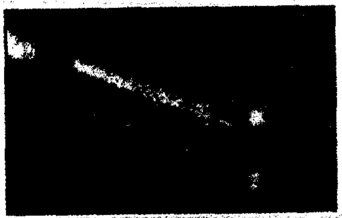
Inside magnification of forceps coil and pull wires with blood and debris.

Jaw with block of debris post disinfection with disinfectant residue.



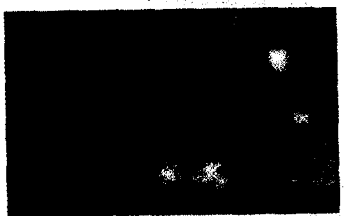
Forceps outside sheath with abrasions from use with scope.

New Units

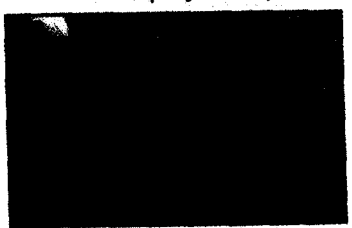


Outside of the jaws new forceps.

Clean forceps jaw cup.



Clean forceps jaw cup.



New forceps needle.

Separated new coils.

A shiny new forceps coil connection.

A new forceps coil connection.

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Editor's note: This article is derived from a poster that was one of two selected as most outstanding at the Association for the Advancement of Medical Instrumentation/US Food and Drug Administration conference, Reprocessing Medical Devices: Designing, Testing, and Labeling, Nov. 5-7, 1997, in Dallas Texas. AAMI (www.aami.org) is located in Arlington, Va.

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Chapter 7

Evaluating the Feasibility of Reusing a Single-Use Device

The reuse committee should perform a feasibility evaluation for each device and model of that device being considered for reuse. While in some cases it may be possible to establish parallels between models, thus simplifying the process, subtle differences in materials or design among models can affect feasibility of reuse.

Recently, the Cleveland Clinic Foundation completed a feasibility study for the reuse of perfusion cannulas. A brief synopsis of this study is presented in Appendix I.

We recommend that the first step of the feasibility evaluation be to contact the device's manufacturer to gain essential product information, including

- the sterilization method used,
- the device's component materials, and
- any recommendations for reprocessing.

Although most manufacturers will decline to provide information that supports reuse of a product they label for single use,[1] some may cooperate on a limited basis. For example, some manufacturers will provide recommendations on resterilizing open, but unused, products. In addition, manufacturers may provide additional insight on why it may be inadvisable to reuse the device — insight that may be valid and deserving of thoughtful consideration, despite the manufacturers' financial self-interest in recommending against reuse.

Next, the reuse committee should assess the reusability of the device being considered and whether the healthcare organization has the resources necessary to make reuse safe and effective. For example:

- Can the device be adequately cleaned?
- Is there a practical way to inspect and test the function of the device?
- Will the device require reconditioning (e.g., sharpening)?
- What method will be used for sterilization/disinfection?
- Is there a practical way to track the number of reuses?
- Can the healthcare organization provide the expertise, staff, and equipment necessary for reuse?

Below we discuss each of these concerns with respect to evaluating a single-use product strictly for its reusability.

Cleaning

The device should be easy to clean. As is true for reusable devices, adequate cleaning entails removal of visible soil from body fluids, tissues, and other debris that remain following use of the device. All surfaces of the device, including channels and lumens that may have been in contact with the patient or physiologic fluids, must be accessible to ensure proper cleaning. Devices with long and/or small-diameter lumens, with rough or textured surfaces and deep grooves or crevices, that are composed of porous materials and constructed with hinges or other features that may interfere with cleaning should probably not be considered. **If the product cannot be adequately cleaned, sterilization will not be reliable, and pyrogenic reactions may occur even if the device is sterile. Moreover, if all potentially contaminated surfaces of a critical or semicritical device cannot be inspected for cleanliness after each use, then it should not be reused.** In evaluating a device for cleaning, take into account the methods available in the healthcare organization and the types of cleaning agents that might be used. Consider features of the device and whether the standard methods used can effectively clean all device surfaces without causing damage. Bear in mind that disassembly for cleaning may not be an option if the device is not intended for disassembly. Even if the device could be disassembled, attempting this may result in damage that could predispose the device to failure during use.

Table 1 provides criteria and recommendations for examining the cleanability of specific categories of single-use devices. It is not, however, an exhaustive list of concerns. Instead, it illustrates common concerns that

Table 1. Assessment of Cleaning Capability

Feasibility Criteria	Recommendations
Laparoscopic Instruments (critical devices [e.g., scissors, forceps, suction-irrigators])	
1. For a device with a lumen: • Can all surfaces likely to be contaminated be visualized for inspection? • Does the device allow the lumen to be flushed from the handle toward the distal end? • Can the device be disassembled to permit cleaning of the lumen? • Are the inner surfaces of the device completely accessible for cleaning with small brushes?	If not, proceed to criteria 3.
2. For a device with linkages, hinges, or articulations that are likely to come in contact with patient tissue or be soiled in use: • Can the device be manipulated so these components can be accessed with fine (dental) brushes for cleaning?	If not, proceed to criteria 3.
3. Does the healthcare organization have the in-house capability to demonstrate that enzymatic solution soaking followed by ultrasonic cleaning (or other applicable cleaning method) can effectively remove soil? If not, has the healthcare organization been able to identify an independent laboratory that can perform this test?	If the answer to these questions is no, the device should not be reused.
Cardiac Catheters, Guide Wires (critical devices [e.g., ablation catheters, EP catheters, PTCA catheters])	
1. Does the device have a lumen open to blood?	If so, the device should not be reused because the lumen dimensions are difficult to access for cleaning and inspection.
2. Does the healthcare organization have in-house expertise, or is there an independent laboratory that can demonstrate which cleaning agents are compatible with the device materials (including adhesives)? Can either provide information on thrombogenicity of materials after exposure to a reprocessing procedure?	If not, the device should not be reused.
3. For PTCA balloon catheters, can the balloon be inflated to confirm that all surfaces are clean?	If not, the device should not be reused.
4. Does the outer surface of the device have a rugose texture (common on many guide wires) that may shield soil from cleaning and harbor microbes?	If so, the device should not be reused.
Rotary Cutting Instruments (critical devices [e.g., burs, drill bits, reamers, shavers])	
1. Are all surfaces likely to be exposed to patient tissue and physiologic fluids accessible for cleaning? For a device with sheathed cutting components (shavers), can the device be disassembled for cleaning?	If not, the device should not be reused.
Respiratory Devices (semicritical devices [e.g., breathing circuits, endotracheal tubes])	
1. Are all surfaces that may come in contact with physiologic fluids accessible for cleaning? Corrugated inner surfaces of breathing circuits may require brushing to ensure that the circuits are adequately clean.	If not, the device should not be reused.

should be addressed when examining the devices listed and was devised by examining some of these single-use products. The examples should serve as a starting point for the reuse committee's feasibility analysis.

Functional Tests and Inspection

Devices that may be nonfunctional or in unsafe condition must be identified and rejected before reuse on a patient. The reuse committee must determine if there are practical functional tests that can be performed on the cleaned instruments to demonstrate that there is no significant loss of function, taking into consideration how the device is used and all facets of its function. For cartridge instruments (e.g., staplers), functional testing may mean testing the entire system, including the staple cartridge, to confirm that the system operates as specified. For some devices, functional tests may be easy to develop; for others, measuring function and identifying degradation in performance may not be possible. The healthcare organization's clinical engineering department or engineering consultants may be helpful in this step. Bear in mind that some functional tests may exist as American Society for Testing

(continued on page 58)

Table 2. Assessment of Inspection and Functional Testing Capability

Laparoscopic Instruments (critical devices [e.g., scissors, forceps, suction-irrigators])

Feasibility Criteria	Recommendations
1. Can the device be visually inspected to verify the effectiveness of the cleaning process before sterilization? (Lumens and other areas that cannot be accessed for visual inspection without destructive methods may make this step impossible for routine intraprocedural testing.)	If not, the device should not be reused.
2. If the device is used for electrosurgical applications: • Can electrical conductivity tests be done to confirm that the device is still suitable for use? • Can visual inspection or other tests be used to confirm that insulating materials are not cracked or otherwise compromised?	If not, the device should not be reused.
3. Are there functional tests addressing the following concerns that can be performed to confirm the device is still fit for use? • Device still operates smoothly? • Device is still compatible with related equipment (e.g., trocar sleeves)? • Components of device still properly aligned?	If not, the device should not be reused.
4. For devices with cutting mechanisms on the distal end (e.g., scissors, punches), can the cutting edges be accessed for adequate sharpness by inspection for chipped or pitted surfaces or burs? Are there other tests that can be used to confirm that the device cuts effectively?	If not, the device should not be reused.

Cardiac Catheters, Guide Wires (critical devices [e.g., ablation catheters, EP catheters, PTCA catheters])

Feasibility Criteria	Recommendations
1. Can the device inspection process detect degradation with reuse? Signs of degradation may include pitting, discoloration, cracking, and breakdown of materials, including adhesives.	If not, the device should not be reused.
2. Is there a way that mechanical properties important to the function of the catheter can be tested? Properties such as torsional rigidity and flexibility should be considered.	These tests should be performed as part of the routine function testing. If there is no way to test, determine how significant the properties are to the application of the device, and use this to decide if reuse is feasible.
3. For balloon catheters, is there a test for leaks in the balloon?	If not, the device should not be reused.
4. For electrode catheters, is there a test that will demonstrate that the catheter conductors are still electrically conductive?	If not, the device should not be reused.

Rotary Cutting Instruments (critical devices [e.g., burs, drill bits, reamers, shavers])

Feasibility Criteria	Recommendations
1. Can magnified visual inspection for burs or chipped cutting edges be used to demonstrate that the device is still sharp enough for reuse? If not, is there another test that will demonstrate that the device is still effective?	If not, the device should not be reused.
2. Does the healthcare organization have a means to verify that device shafts are still true (in alignment)?	If not, the device should not be reused.
3. Can visual inspection be used to verify that the device was adequately cleaned? Are all surfaces that are likely to be contaminated accessible for inspection?	If not, the device should not be reused.
4. Does the healthcare organization have a way to inspect devices for damage that may lead to intraoperative fracture?	If not, end users must decide if device fracture during use represents an unacceptable risk.

Respiratory Devices (semicritical devices [e.g., breathing circuits, endotracheal tubes])

Feasibility Criteria	Recommendations
1. Does the healthcare organization have a method to test breathing circuits or endotracheal tubes for leaks?	If not, the device should not be reused.
2. Does the healthcare organization have a method to test the security of device connections to equipment used for ventilation? These tests should also look for leaks.	If not, the device should not be reused.

(continued from page 56)

and Materials (ASTM) standards. Otherwise, the reuse committee may need to develop performance tests, using tests on new devices to establish the criteria for acceptability as a benchmark. Table 2 on page 57 presents a detailed approach to assessing functional testing and inspection capability for specific categories of single-use devices.

Wear generated by use or cleaning may abrade device surfaces and make adequate cleaning in future reprocessing impossible. Therefore, devices being reused will need to be inspected after cleaning. For some devices, this may be as basic as inspecting the device's surfaces under magnification. More complex devices may require more specialized equipment. Devices subjected to cyclic loading (e.g., drills, saw blades, burs, reamers) may sustain subtle damage with use that could result in failure during the next application. Magnified visual examination by skilled inspectors may reveal minute cracks or other signs that failure is imminent. **Devices under consideration should allow for good visual inspection and easy validation of safe and effective function.**

Reconditioning

Some devices may require sharpening or some other form of reconditioning before they can be reused. To ensure smooth operation, some devices with moving parts will require lubrication between uses. For these devices, a lubricant that is compatible with the device's component materials and that will not interfere with or be degraded by sterilization must be selected. Instruments used to cut or puncture tissue may need to be sharpened at least occasionally if not before each reuse cycle. Because specialized equipment may b required to sharpen some instruments, it may not b practical for a healthcare facility to try to undertak this type of reconditioning in-house. In addition, it i difficult to judge sharpness, and there are no standard ized methods to gauge whether a device is adequatel sharp before use. For instruments with cutting sur faces that require periodic sharpening, it may be bes to rely on an outside contractor to provide this servic or not consider them for reuse.

Sterilization

While there may be some exceptions, most items considered for reuse fall into the Centers for Disease Control and Prevention (CDC) category of critical devices and thus must be sterilized. A variety of sterilization methods are available to healthcare organizations. While steam sterilization is generally considered the method of choice within healthcare facilities, the high polymeric material content of many single-use devices requires a low-temperature sterilization method. Although there are liquid low-temperature sterilization methods available, gas sterilization methods are preferred for many critical devices because they can be more easily monitored with biological indicators, and devices can be packaged for poststerilization storage. EtO is the predominant sterilization method used to sterilize heat-labile devices. Newer gas sterilization techniques like hydrogen peroxide vapor/plasma sterilization (Advanced Sterilization Products' STERRAD) and peracetic acid vapor/plasma sterilization (AbTox's Plazlyte) have recently been introduced. However, the base of information relating to material compatibility is much more extensive for EtO. There are also a number of 100% EtO systems and systems

Table 3. Assessment of Sterilization or High-Level Disinfection Capability

Feasibility Criteria	Recommendations
Critical Device Sterilization (e.g., laparoscopic instruments, cardiac catheters, rotary cutting instruments)	
Can the healthcare organization or an independent laboratory determine if there is unacceptably high residual EtO, ethylene chlorohydrin, or ethylene glycol in components of EtO-sterilized devices? (Methods are outlined in AAMI ST29-113 and ST30-113 documents.)	If not, the device should not be reused. This test should be done during validation testing of the proposed reuse process and periodically after process implementation.
Can the healthcare organization or an independent laboratory determine if levels of pyrogens on sterilized products are acceptably low? (Limulus Amebocyte Lysate test method is described in *The U.S. Pharmacopeia*, USP 23-NF 18, chapter 161.)	If not, the device should not be reused. This test should be done during validation testing of the proposed reuse process and periodically after process implementation.
Semicritical Device Sterilization or High-Level Disinfection (e.g., breathing circuits, endotracheal tubes)	
Can the healthcare organization or an independent laboratory measure sterilant or high-level disinfectant residues in the device?	If not, the device should not be reused. This test should be done during validation testing of the proposed reuse process and periodically after process implementation.

Table 4. Compatibility of Commonly Used Plastics with Environmental Conditions Involved in Various Sterilization and Disinfection Processes

Material	Steam	EtO	Glutaraldehyde	Comments
Vinyls:				
unplastisized polyvinyl chloride (rigid PVC)	–	*	+	
plastisized polyvinyl chloride (flexible PVC)	*	*	+	
polyvinylidene chloride (PVdC)	–	+	+	
Olefines:				
polyethylene, low density (LDPE)	–	+	+	
polyethylene, high density (HDPE)	–	+	+	
poly(methyl pentene)	+			
polypropylene	+	+	+	
ethylene/vinyl acetate (EVA)	–	+	+	
Styrenes and copolymers:				EtO: note some diluent gases may cause crazing of some polystyrenes. SAN may be crazed by excess EtO exposure.
polystyrene	–	+	+	
styrene/acrylonitrile (SAN)	–	*	+	
Acrylics:				
polymethyl methacrylate cast sheets	–	+	+	
polymethyl methacrylate molding powders	–	+	+	
Polyamides:				
nylon 6	+	+	*	Glutaraldehyde: some grades of nylon have high water absorption.
nylon 66	+	+	*	
nylon 610	+	+	*	
nylon 11	+	+	*	
Fluorocarbon polymers:				
polytetrafluoroethylene (PTFE)	+	+	+	
polytrifluorochloroethylene (PTFCE)	+	+	+	
fluorinated ethylene/propylene resins (FEP)	+	+	+	
Polyesters:				
polyester resins	–	+	+	Steam: heat-shrinkable film will contract substantially at >80°C.
polyethylene terephthalate	+	+	+	
Acetals:				Glutaraldehyde: avoid acidic mixtures.
polyformaldehyde	*	+	*	
acetal copolymers	+	+	*	
polycarbonate	*	+	*	Glutaraldehyde: not resistant to alkali. Limited resistance to detergents.
epoxide resins	*	+	+	Steam: some grades of high temperature resistance are available; others will not withstand boiling water.
polyurethane foams, flexible and rigid	–	+	*	Thermal properties vary with type. Glutaraldehyde: may be affected by acids or alkalies. Not attacked by detergents.
phenol formaldehyde resins (PF)	+	+	*	Glutaraldehyde: not resistant to acids.
urea formaldehyde resins (UF)	+	+	*	
melamine formaldehyde resins (MF)	+	+	*	
silicone rubbers	+	+	*	

Key: + = suitable. * = borderline; suitable in some circumstances, not in others. – = unsuitable.

Source: Adapted with permission from *Biomed Eng* 1970 Sep.

that use hydrochlorofluorocarbon (HCFC)- and CO_2-diluted EtO currently being used in healthcare facilities. Because of the variety of EtO sterilants, we recommend that device-material compatibility be evaluated with the EtO system that is proposed for reprocessing.

The appropriate method of sterilization or disinfection must be compatible with the device's materials (i.e., must not degrade them), must not leave behind a toxic residue, and must not affect the function of the device. Ideally, the method of sterilization should be discussed with the manufacturer, but as previously noted, many manufacturers may be reluctant to provide such information. Table 3 on page 58 presents feasibility criteria to examine when assessing the healthcare organization's ability to adequately sterilize single-use devices.

Sterilant/material compatibility is of particular concern for polymeric materials because there are a multitude of varieties and formulations. Thus, it is advisable to test the compatibility of materials with the specific sterilization process to be used. While the best source of information related to material/sterilant compatibility is the manufacturer, information from resources like that presented in Table 4 on page 59 can be helpful, provided the material composition of the device is known. This information may be used as an initial screening tool to warn of potential incompatibilities.

Polymeric materials present in single-use devices can retain hazardous levels of sterilant residues, which can cause chemical burns or severe reactions in patients. Sterilant residues are generally less of an issue for metals used in medical devices. If the material composition of the device is known, technical representatives from the sterilizer manufacturers may be able to provide information about whether it is compatible with the process used with the sterilizer. Product packaging inserts may also provide information about how the device was originally sterilized.

Selection of sterile packaging must also be consic ered when choosing a method of sterilization. Th reuse committee should consider packaging material available to the healthcare organization and asses their compatibility (e.g., size, configuration, aeratio time) with the device and reprocessing methods.

In examining the steps required to safely reuse th single-use device under consideration, the reuse com mittee should be thinking about whether the health care organization has the necessary expertise, staff and equipment to develop and implement the reus process. The reuse committee needs to examine the organization's resources and determine if outsourcing of some aspects of reprocessing may be acceptable. For example, the analysis of the device for its compatibility with proposed cleaning, disinfecting, or sterilizing agents may require expertise beyond that available in the organization. Should that be the case, it may make sense to seek assistance from independent laboratories to aid in the development of some procedures. Proposed procedures may suggest a need for specialized equipment to clean or recondition a reused single-use device — equipment that may be quite expensive. Moreover, the staff required to operate the equipment and handle the reprocessing of the single-use device may not be available, especially in facilities that have experienced downsizing. In Chapter 10, we discuss third-party reprocessing companies that may be able to help an organization address some of these concerns.

Note

1. Kotilaimen H. Resterilization: is anybody out there watching? *Hosp Mater Manage Q* 1988 Feb;9(3):27-35.

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Quality Assurance on Reprocessing Accessories for Flexible Endoscopes - Just How Clean are Cleaned Instruments Really?

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Quality Assurance on Reprocessing Accessories for Flexible Endoscopes – Just How Clean are Cleaned Instruments Really?

The efficacy and safety of a to a large extent standardised manual procedure for reprocessing artificially contaminated endoscopy accessories were investigated with the aid of the radionuclide method and of microbiological procedures. Based on data in the literature, the costs were also taken into consideration, in order to be able to estimate the economic feasibility of reprocessing. Neither adequate cleaning nor adequate disinfection was achieved in the majority of the medical devices inspected. Single-use papillotomes could no longer be rinsed in some cases after contamination. Of the 90 accessories that had undergone preliminary treatment in this manner, only 30 could be rendered free of microbes in the half cycle during steam or EO sterilisation. It was demonstrated that often the design of the instruments impeded reliable reprocessing. It was furthermore established that the potential savings were considerably lower than those commonly assumed.

Keywords: medical devices, endoscopy accessories, cleaning, disinfection, sterilisation, quality assurance

1 Introduction

Reports on cross contamination and infections with *Helicobacter pylori* or with the hepatitis C virus caused by reprocessed accessories for flexible endoscopes have been focusing attention increasingly in recent times on the quality of reprocessing for these instruments (1, 2). In addition to the problem of an instrument's design that is scarcely amenable to cleaning, the manufacturer's instructions for reprocessing these instruments often appear to be inadequate or hardly practicable in the everyday hospital setting.

Economic pressures and the major price differences between single- and multiple-use instruments provide a powerful incentive to reprocess single-use instruments, in order to reduce costs. To comply with legal demands for a validated reprocessing method (3), microbiological investigation methods are generally employed. These have been devised for the investigation of disinfection and sterilisation, i. e. antimicrobial processes, and are also suited to, and endowed with the necessary power for this field of application. In the absence of suitable alternatives, these methods are being employed to check the quality of cleaning, despite the fact that only subject to certain conditions do they permit sound conclusions to be drawn.

Set against this background, a study was conducted, to elucidate the potentials and limitations residing in the reprocessing of endoscopic accessories, at the Prüfzentrum für Medizinprodukte (PMP: Test Centre for Medical Devices) – a collaboration project by the Naturwissenschaftliches und Medizinisches Institut (NMI: Scientific and Medical Institute), Reutlingen, the Sektion and Steinbeis-Transferzentrum for Minimally Invasive Surgery and the department of hospital infection control of the University Hospital Tübingen.

The aim of the study was to ascertain the safety offered by the reprocessing of endoscopic accessories following a standardised reprocessing method, which was based on the customary hospital practice. To this effect, instruments were investigated which, by virtue of their intended clinical use and as per the classification by Spaulding (4) had to be used in a sterile condition, as they would penetrate the mucosa on being used as directed. Both multiple- and single-use instruments were selected. Attention was paid to ensuring that both types of instruments had been designed for the same application spectrum. According to the European requirements (5) and the German medical devices legislation (6), each reprocessing step, i. e. cleaning, disinfection and sterilisation, must be validated with suitable processes.

A further imperative targeted by the study was to highlight differences in the quality of reprocessing and to clarify whether and under what circumstances a safe device could be guaranteed. A preliminary cost evaluation was intended as a means of clarifying the economic feasibility of reprocessing.

2 Economic Feasibility Considerations

Various studies, both in the USA and in Germany, have in recent times focused on the financial investments for reprocessing endoscope accessories, with the reprocessing costs of reusable instruments being compared with those incurred on using single-use instruments as directed. In the case of reprocessing of single-use items, the same costs were assumed as those incurred for reprocessing reusable instruments.

Having compared the costs for employment of single-use biopsy forceps and reprocessable biopsy forceps,

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Table 1 Cost comparison between reusable and single use biopsy forceps

Study	Olympus	Yang	Yang	Birkner 1	Birkner 2	Birkner 3	Birkner 4
Device	Biopsyforceps	Biopsyforceps	Biopsyforceps	Biopsyforceps	Biopsyforceps	Biopsyforceps	Biopsyforceps
Purchase costs	368.- DM	415 $	38 $	38.81 DM	449.46 DM	563.50 DM	353.12 DM
Repair costs	–	–	–	–	1 352.7 DM	221.35 DM	–
Number of uses	27	19	1	1	212	68	141
Purchase and repair costs	13.63 DM	21.85$	38 $	38.81 DM	8.70 DM	11.53 DM	2.51 DM
Reprocessing costs	unknown	16.56$	–	0.01 DM	3.33 DM	17.33 DM	14.36 DM
Costs per use		38.40 $	38 $	38.82 DM	12.03 DM	28.86 DM	16.87 DM

Table 2 Cost comparison between reusable and single use snares

Study	Schwark	Schwark	Birkner 1	Birkner 2	Birkner 3	Birkner 4
Device	Snare	Snare	Snare	Snare	Snare	Snare
Purchase costs	390.30 DM	56.35 DM	47.90 DM	390.31 DM	400.00 DM	405.95 DM
Number of uses	9	1	1	11	31	43
Costs per use	43.37 DM	–	–	35.95 DM	13.06 DM	9.44 DM
Reprocessing costs	9.22 DM	–	–	4.95 DM	16.18 DM	19.84 DM
Costs per use	52.59 DM	56.35 DM	47.90 DM	40.90 DM	30.39 DM	30.64 DM

Yang (7) came to the conclusion that only after a 20-fold deployment of reusable instruments could a price advantage be obtained over the use of single-use forceps. The observed service life of the reprocessed forceps was on average 20 deployments, with malfunctioning rapidly increasing already as from the 16th deployment. In addition to costs, Yang also focused on the quality of reprocessing and, after reprocessing, discovered on many locations on the reusable biopsy forceps microscopically still visible contaminants, deposits and rust. Some of the inspected instruments also evidenced kink points, which in some cases were possibly responsible for malfunctioning.

Yang's findings are in concordance with those of a study conducted in a gastroenterological practice in Germany with instruments of the same type (8). The first breakdowns were registered here already after the 12th use. But some forceps were still fully functional after 45 deployments. On completion of the study, 189 interventions had been performed with a total of 7 forceps, corresponding to an average service life of 27 deployments. No study indicated how many biopsies were conducted during an intervention with a single forceps.

Schwarck (9) compared in a study the costs for single- and multiple-use snares. Here too it was revealed that the potential savings per deployment were greatly dependent on the service life of the snares. Depending on manufacture, the cost savings per deployment ranged between DM 3.76 and DM 11. 65. In the case of one type of snare, the costs of DM 17. 92 incurred during use of reusable snares were even markedly higher than those of single-use snares.

A further study (10) at two hospitals and one medical practitioner's office produced similar findings as regards the costs for reusable polypectomy snares. Since the single-use snares used here as a comparison could, however, be procured for markedly more favourable prices, the deployment costs were accordingly lower and were less than those incurred for use of reusable snares.

On the other hand, the savings potential residing in reusable biopsy forceps in this study was greater than that of Yang's study. The costs per establishment ranged between DM 12.03 and DM 28.86 per deployment compared with DM 38.82 and DM 44.01 for use of single-use forceps.

The major differences in costs can be explained, on the one hand, by the markedly greater frequency of use which, however, was mostly associated with high repair costs. On the other hand, the cost component for reprocessing was also apparent, ranging in Germany between DM 3.33 and DM 17.33, but in the USA between $ 10.83 and $ 16.80 per reprocessing procedure. Major study-dependent differences have also been discerned as regards the procurement prices, both for reusable and single-use instruments (table 1 and 2).

Some users have hopes for making additional savings by repeatedly using single-use items. In general, after once using these instruments the user has the impression that further use is still by all means possible. A basic prerequisite for safe reuse is, however, validated reprocessing procedures and a high-performance quality assurance system, which monitors the success

Table 3 Description and material of the tested devices

	Single use	Length [mm]	⌀ [mm]	Luer-Lock	Internal Lumen	Interior	Cover sheet
Biopsy forceps	Yes	2400	2.2	No	1	2 polyfile steel wires	covered metal coil
Biopsy forceps	No	2300	2.2	No	1	2 polyfile steel wires	metal coil
Papillotoms	Yes	2000	2.0	2	3	Cutting wire	PTFE tube
Papillotoms	No	1820	1.8	1	1	Cutting wire	PTFE tube
Dormia Basket	No	2100	2.4	1	1	polyfile steel wire with basket	PTFE tube

of cleaning and makes provision for reproducible and reliable findings. Hence to the costs of reprocessing must also be added the costs of process validation and of implementation and maintenance of the quality assurance system.

The Canadian Healthcare Association estimated the validation costs alone to be US$ 7584 per instrument type (11). In a similar study (12), these costs were even calculated to be between US$ 39 000 and 51 000 depending on the instrument type. A German company conducting validated reprocessing on a wage basis estimates similar costs. The validation costs alone are around DM 23,000 per device group. The costs for process development, calibration of systems and test equipment, monitoring of process parameters, personnel training etc. must still be added.

3 Material and Methods

3.1 Inspected Instruments

Various types of instrument designs were inspected to determine their suitability for reprocessing. By way of example, the results obtained for 2 biopsy forceps and 2 papillotomes are described here, consisting of one single-use and one reusable instrument in each case. In addition, one reusable dormia basket was included in the inspection (table 3). The single-use instruments were delivered in a sterile condition, while the reusable instruments were sterilised before use with steam as per the manufacturer's instructions.

3.2 Methods of Detection

To verify the cleaning outcome, various methods of detection were employed and were selected as a function of their power.

3.2.1 Radionuclide Method (RNM)

The radionuclide method (RNM) serves to furnish proof of the cleaning action. A contamination of coagulable human blood with addition of radioactively marked macroalbumins permitted a quantitative evaluation of the cleaning quality with spatial resolution (13). Based on our own investigations, a surface was defined as being clean if the residual contaminants were not more than 5 counts per second.

3.2.2 Microbiological Inspection Methods

To verify the disinfection outcome, *S. aureus* ATCC 6538 and *P. aeruginosa* ATCC 15442 (10^6 to 10^7 cfu/ml baseline suspension) were employed according to the recommendation of the German Society for Hygiene and Microbiology (DGHM) (14). The instruments were contaminated with a suspension of heparinised sheep blood with addition of protamine and with the corresponding test organisms (15).

To verify the results of sterilisation, spore suspensions (0.5 to 5 × 10^6/ml) of *B. stearothermophilus* ATCC 12980 were used for steam sterilisation and of *B. subtilis var. niger* ATCC 9372 (producer: Simicon, Munich) for gas sterilisation. The instruments were contaminated only with the spore suspension without blood challenge. To ascertain the recovery rate of the test organisms, corresponding investigations were conducted.

3.2.3 Test Procedure

The instruments were contaminated in a simulation model mimicing a worst case scenario. This model consists of a plexiglass box, with 30 cm long silicon tubes fitted on its upperside, via which the instruments are introduced into the box. Inside the box is a glass beaker in which the jaw parts of the instruments are immersed. A seal at the distal end of the tubes prevents loss of gas on insufflating air up to 15 mm Hg, in order to simulate the intraluminal pressure.

The markers needed for the individual detection methods are added to the coagulable blood and injected via another tube into the glass container in the box. The functional parts of the instruments are fully immersed in the blood and are repeatedly manipulated. As soon as the blood has coagulated, the instruments are removed from the box.

The reprocessing procedure has been standardised according to manufacturers' instructions, while calling upon our own experiences:
- 3 min preliminary rinsing with water at 30 °C
- 4 × rinsing of instruments (syringe) with enzymatic detergent (Terg-A-Zyme, Alconox, Inc., New York) if possible

- 10 min immersion in enzymatic detergent
- 5 min ultrasound with enzymatic detergent
- 3 min rinsing with tap water (on the outside)
- irrigation (syringe) with tap water, if possible
- drying by blowing out with compressed air
- drying of outside (towel)

The following concomitant measures were taken for disinfection after cleaning:
- Filling of the instruments (syringe) with 2% glutaraldehyde solution (Cidex; manuf.: Johnson & Johnson Medical, Arlington, Texas)
- Immersion in glutaraldehyde solution, 25 min at 20 °C (pH value: 7.9–8.9)
- 3 min rinsing with warm water at 30–35 °C
- Blowing out of internal lumens with compressed air
- Drying of instruments with compressed air

Sterilisation of the contaminated instruments was effected in the half cycle with steam (134 °C) or ethylene oxide (6% EO, 94% CO_2).

3.2.4 Investigation of Clinically Deployed Instruments

To furnish at least orientational data on the reprocessing quality of endoscopic accessories in clinical practice, reprocessed "critical" instruments from different hospitals were investigated for sterility. The instruments – predominantly biopsy forceps – had either been sterilised with steam or gas or subjected to high-level disinfection.

Inspected concomitantly were 10 single-use forceps, which had been reprocessed by a contractor. The instruments were dismantled into segments under sterile conditions in the laboratory and placed in typticase soybean broth. For some instruments, the segments were combined in sections in order to obtain a certain spatial resolution. The size of the entire 3 sections was chosen according to the RNM findings.

4 Results

4.1 Cleaning

In all cases, 7 instruments of each type were tested with RNM. With the exception of 2 papillotomes, the limit value of 5 counts/s was not achieved by any of the medical devices inspected. The instruments were considerably above the limit value in some cases. For example, the dormia basket after a very high baseline challenge, pointing to a large internal lumen, harboured more test contamination after cleaning than all other instruments before cleaning. The reusable biopsy forceps nonetheless achieved an average reduction to 13 counts/s, while there was hardly any perceptible reduction of contamination evidenced in the single-use version (figure 1).

The spatial resolution of the RNM provides information on the distribution of the contamination. Particularly

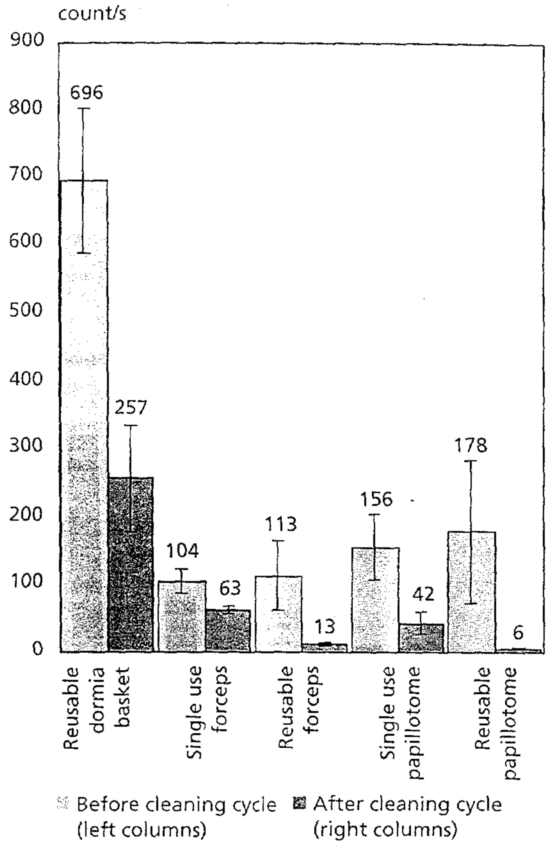

Figure 1 Mean activity

conspicuous in this respect is the single-use forceps which, while showing a slight reduction in activity, the latter was distributed over a greater length (figure 2).

4.2 Disinfection

The first test with *P. aeruginosa* for single-use instruments furnished such poor results that testing was discontinued. The single-use papillotomes could no longer in some cases be rinsed after contamination, with complete disinfection being achieved only for one instrument. Neither could one of the reusable papillotomes be rinsed, whereas the other 5 instruments of similar design were all satisfactorily disinfected (table 4).

4.3 Sterilisation

Examination of the control instruments showed that not all the instruments achieved the required baseline contamination of > 6 logs. Despite the, in some cases, markedly lower microbial contamination, it was possible to sterilise only 30 of the total 90 instruments (table 5).

4.4 Clinically Deployed Instruments

Only some of the instruments reprocessed within the hospital were sterile. Of the 25 multiple-use biopsy forceps inspected, 5 were sterile, 12 evidenced slight growth (less than 100 cfu/device); streptococci, enterococci or pseudomonads were detected in 7 devices

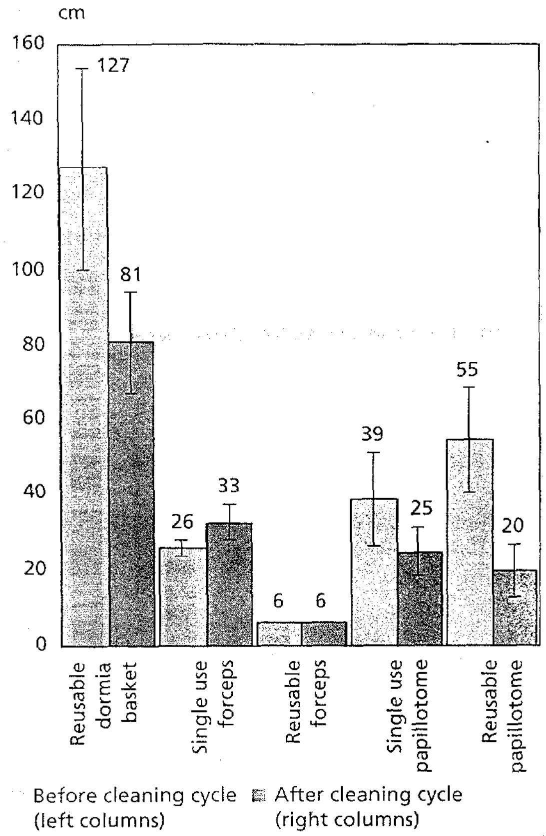

Figure 2 Mean distribution of contamination

(table 6). Overall, 10 reprocessed single-use biopsy forceps were also inspected. As opposed to the reusable forceps, these had been sterilised with EO. Only one forceps was sterile, with all others evidencing residuals microbial counts up to 50 cfu/device.

The scanning electron microscopic examination of the pull wire of a biopsy forceps in new condition and after reprocessing also proves that reprocessing was not successful (Figures 3 and 4).

5 Discussion

In view of the high costs for validation and quality management, reuse of single-use articles appears reasonable only in the case of expensive devices. At the same time, a certain minimum requirement must be assured, in order to distribute the costs among as many applications as possible. If the device is changed by the manufacturer, a new validation procedure is required, something which should be borne in mind in respect of the ephemeral life span of many medical devices.

The adoption of already validated procedures can be contemplated only if identical conditions are prevailing on one's own facilities; otherwise one has to conduct one's own validation. Our investigations also clearly indicate that even the manufacturers' instructions for reprocessing reusable instruments are totally inadequate. We are not aware of any detailed national guidelines for verification of cleaning.

Table 4 Results of the disinfection experiments

		Pseudomonas aeruginosa Disinfection results			*Staphylococcus aureus* Disinfection results		
Device	Reusable	1	2	3	1	2	3
Biopsy forceps	No	– (0)	– (0)	– (0)			
Biopsy forceps	Yes	++	++	++	++	++	++
Papillotom	No	++	– (2.96)	– (0)			
Papillotom	Yes	– (4.52)	++	++	+	+	+
Dormia basket	Yes	++	+	++	++	++	++

++ = reduction > 5 lg (no growth in quantitative and enrichment cultures)
+ = reduction > 5 lg (growth of test organisms in enrichment cultures only
– = reduction < 5 lg (reduction factor in brackets)

Table 5 Results of the sterilisation experiments

		B. subtilis ETO sterilisation results			*B. stearothermophilus* Steamsterilisation results		
Device	Reusable	Contr. (cfu)	Growth	No growth	Contr. (cfu)	Growth	No growth
Biopsy forceps	No	6.14	7	2	4.36	4	5
Biopsy forceps	Yes	4.68	9	0	4.24	3	6
Papillotom	No	6.18	6	3	5.95	8	1
Papillotom	Yes	6.41	3	6	5.30	9	0
Dormia basket	Yes	5.95	2	7	6.34	9	0

Table 6 Results of the test with clinically used devices. Number of tested devices: 57, sterile: 15, unsterile: 42.

	Third Party Reprocessor		USA		Japan		Germany	
	sterile	unsterile	sterile	unsterile	sterile	unsterile	sterile	unsterile
Single Use Biopsy Forceps	1	9						
Reusable Biopsy Forceps	2	8	2	5	3	11	2	5
Single Use Ultratome								1
Reusable Papillotome								1
Reusable Dormia basket							1	
Single Use Dilatation Ballon	4	1						
Single Use Guidewire		1						
Total	7	19	2	5	3	11	3	7

For a number of reasons, manual reprocessing was chosen for the present investigation: many hospitals have no suitable washer/disinfectors for reprocessing endoscopes, cleaning performance varies for the different types of washer/disinfectors, and finally the advantage of manual reprocessing resides in the fact that a very high cleaning pressure (up to 5 bar) can be achieved, which is generally not possible in washer/disinfectors (0.3 to 0.5 bar). Ultrasonic cleaning was limited to 5 minutes, since a longer sonication period results in marked heating of the cleaning water, resulting in turn in protein denaturation and hence detracting from the cleaning performance.

The business management data collected here show that repeated use of the inspected single-use devices do not hold out prospects for financial savings due to the high validation costs. The differences in procurement prices of in some cases identical items, show that there is currently great movement in the market. A realistic cost estimate must absolutely take account of the individual needs of individual establishments. Skilled negotiations and corresponding acceptance commitments can secure considerable discounts in some cases. It is therefore difficult to estimate costs on a flat rate basis.

Especially the service life of the instruments, which ultimately exerts greatest influence on the costs, is frequently overestimated. Generally it is shorter than that normally assumed and hence poses a certain risk when making calculations. The service life of up to 200 deployments and more given in some studies is made possible only at the cost of high repairs. Concomitantly, logistics costs (e. g. dispatch for repair) are not featured in any study. Neither are costs emanating from prolonged operations due to failure of instruments taken into consideration. The potential savings, which even now are in some cases small, are quickly negated by these costs. Single-use instruments, conversely, permit accurate calculation of costs.

If in the case of some devices, the paucity of potential savings is a disincentive to using reusable endoscopy accessories, their use is all the more questionable from the hygienic viewpoint. None of the inspected instrument types could be reprocessed reliably and safely. This failure was attributed less to an inadequate cleaning technique than to the instrument design.

If one considers the cleaning results obtained for the single-use biopsy forceps it becomes clear that the enzymatic detergent certainly does generate its action. The blood coagula were dissolved and the once again liquefied contaminants were able to spread out further in the instrument. The forceps makes no provision for cleaning the internal lumen, hence the dissolved soils are inevitably retained within the instrument. The ensuing disinfection results in renewed protein denaturation, which in all probability prevents the disinfectant from being distributed in the instrument. Conversely, while it was possible to rinse the dormia basket, adequate cleaning could not be assured due to the instrument design (247 counts/s). On the other hand, the disinfectant could apparently reach all inner surfaces, making provision for an adequate disinfection outcome.

The unsatisfactory sterilisation results achieved for these instruments are not unexpected, since effective cleaning is the prime precondition for successful sterilisation. It is precisely this example that clearly indicates that adequate cleaning cannot be necessarily inferred from good disinfection results. Furthermore, there were no reprocessing instructions available for this device. The manufacturer pointed out that the label "autoclavable" was enough. On further scrutiny, it was established that the device could be dismantled, thus considerably enhancing the cleaning effect. However, two persons were needed to assemble the instrument, as also confirmed by experienced endoscopy nurses.

Inspections of instruments reprocessed in the hospital confirm the impression of a completely inadequate outcome quality. For this reason, the following conclusions must be drawn:

- Due to the design features of these devices, effective quality assurance is currently not possible when reprocessing endoscopy accessories.

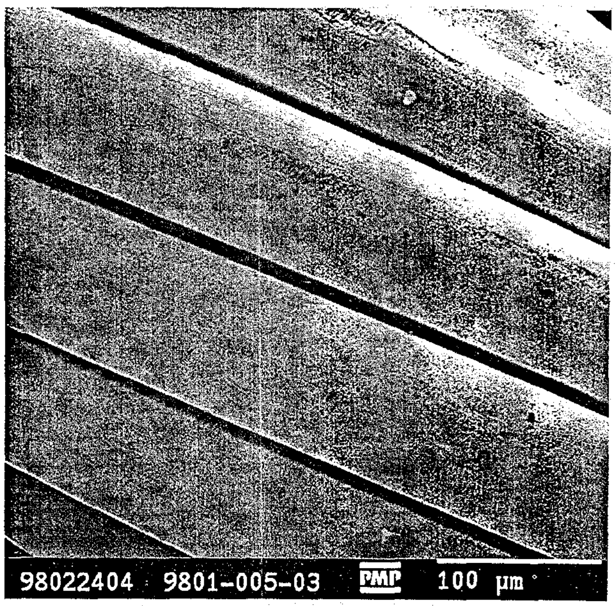

Figure 3 Pullwire in a reprocessable biopsy forceps in initial setting; location: 100 mm above the tip.

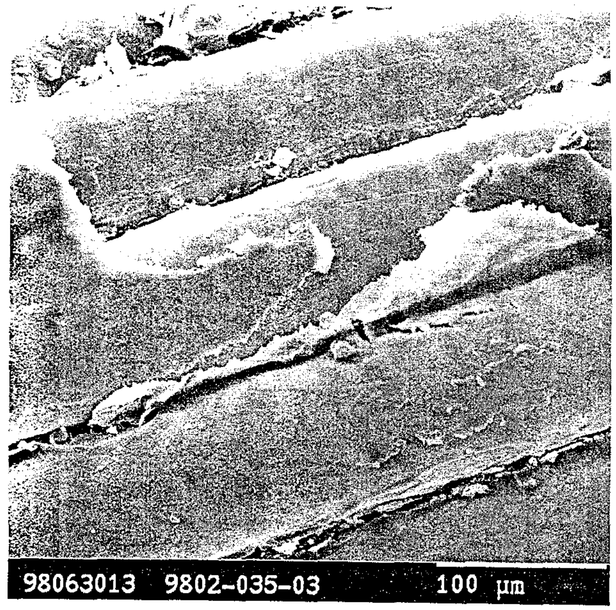

Figure 4 Pullwire in biopsy forceps, reprocessed after clinical use; location: 100 mm above the tip.

- The potential savings to be made from reprocessing single-use medical devices are on closer scrutiny – at least in the domain of endoscopy – essentially lower than generally assumed.
- The deployment costs for single- or multiple-use instruments often differ only minimally.
- As regards risk calculation, one must ask oneself whether, in view of the low potential savings, a risk to the patient's health should be recklessly disregarded.

Acknowledgement

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References/Literatur

1. Bronowicki JP, Venard V, Botté C et al.: Patient-to-patient transmission of hepatitis C virus during colonoscopy. N Engl J Med 1997; 337: 237–240.
2. Akamatsu T, Tabata K, Hironga M et al.: Transmission of Helicobacter pylori infection via flexible fiberoptic endoscopy. Am J Infect Control 1996; 24: 396–401.
3. Verordnung über das Errichten, Betreiben und Anwenden von Medizinprodukten (Medizinprodukte-Betreiberverordnung – MPBetreibV). BGBl 1998, I, 1762.
4. Spaulding EH. Chemical disinfection of medical and surgical materials. In: Lawrence CA, Block SS (eds.): Disinfection, sterilization and preservation. Philadelphia: Lea and Febiger, 1968: 517–531.
5. Richtlinie des Rates über Medizinprodukte vom 14. Juni 1993 (93/42 EWG). Abl EG 1993, Nr L 169, 1.
6. Gesetz über Medizinprodukte (Medizinproduktegesetz – MPG). BGBl 1994, I, 1963.
7. Yang RA: Cost and performance evaluation of disposable and reusable biopsy forceps in gastrointestinal endoscopy. Abstract Nr. 135; Digestive Disease Week, 1997 Washington D.C.
8. Waldherr A, Fallstudie: die Biopsiezange; Olympus informiert 1/98: 4–5.
9. Schwark S: Einmalartikel oder Wiederaufbereitung. Endoskopie heute 1998; 11: 14–20.
10. Birkner B: Kostenvergleichsstudie verschiedener endoskopischer Accessoires in der gastrointestinalen Endoskopie. Gastro-Nachrichten 1998 Nr. 20: 3–6.
11. Canadian Healthcare Association: The reuse of single use medical devices: Guidelines for Health Care Facilities. Ottawa: CHA Press, 1996.
12. Reichert M: Single use devices – Program development. AAMI & FDA Meeting 14.–16. Nov. 1996, Los Angeles.
13. Schrimm H, Sieber JP, Heeg P, Roth K, Müller-Schauenburg W, Keller KD, Bueß G: A new method for validating and verifying the cleaning of tubular instruments. Zentr Steril 1994; 2: 313–324.
14. Deutsche Gesellschaft für Hygiene und Mikrobiologie: Richtlinie für die Prüfung und Bewertung chemischer Desinfektionsverfahren. 1. Teilabschnitt (Stand 1. 1. 1981). Stuttgart: Fischer, 1981.
15. Deutsche Gesellschaft für Krankenhaushygiene: Prüfung und Bewertung der Reinigungs- und Desinfektionswirkung von Endoskop-Dekontaminationsautomaten sowie -Desinfektionsautomaten. Hyg Med 1995; 20: 40–47.

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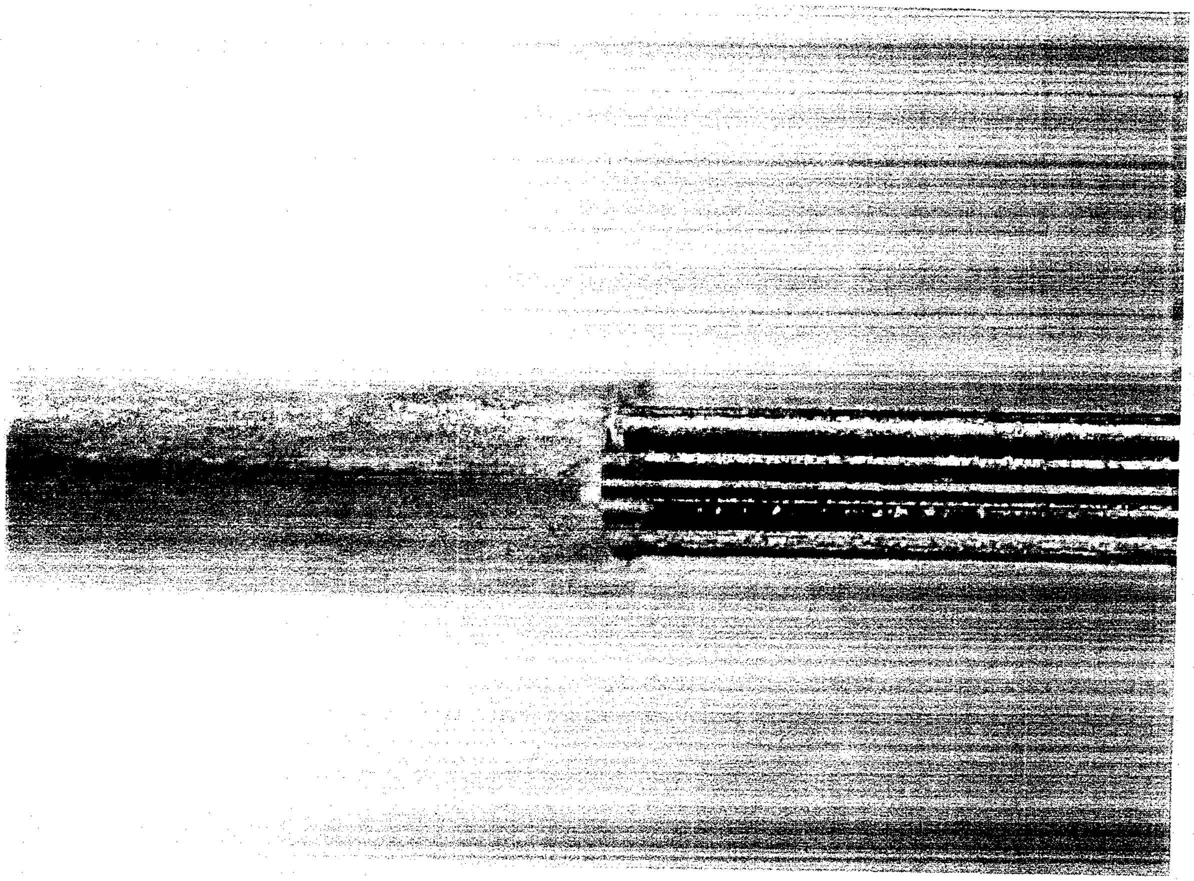
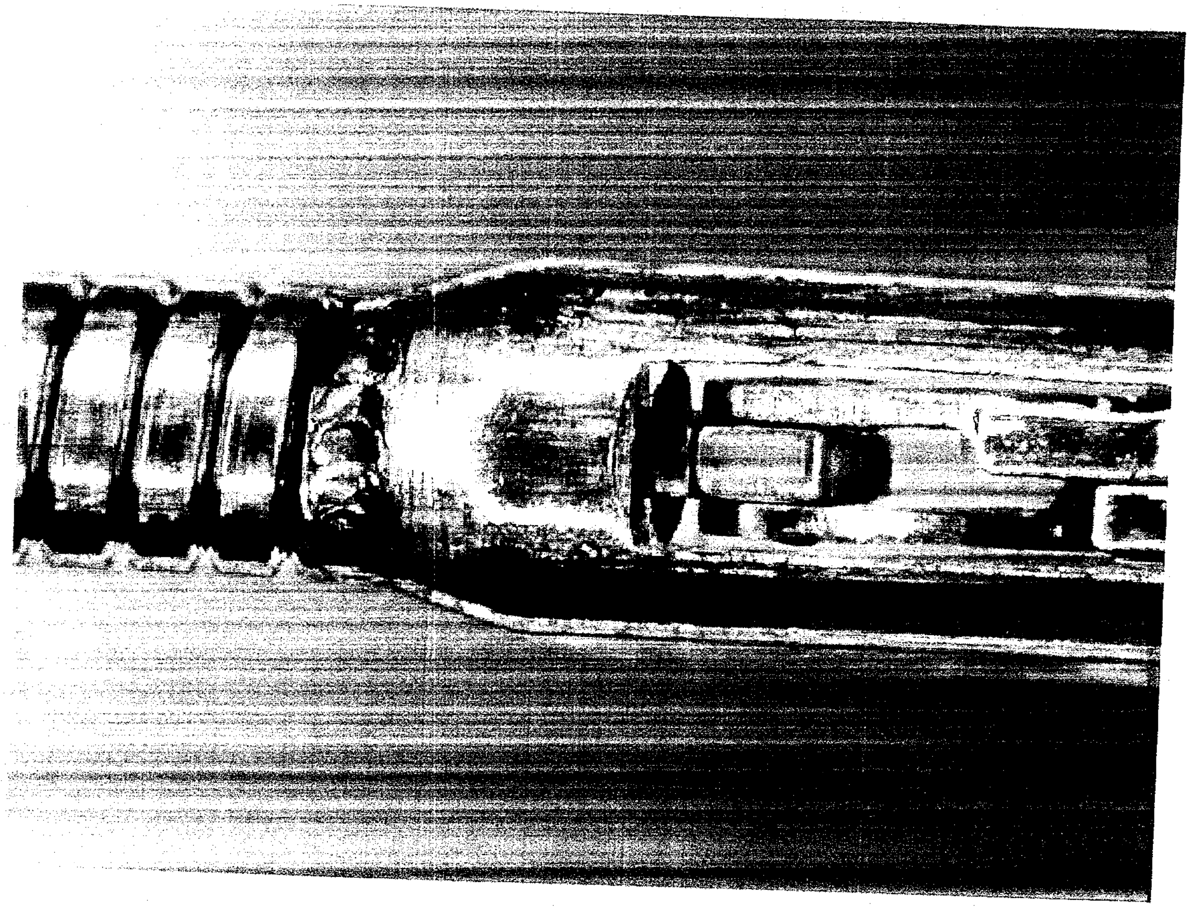


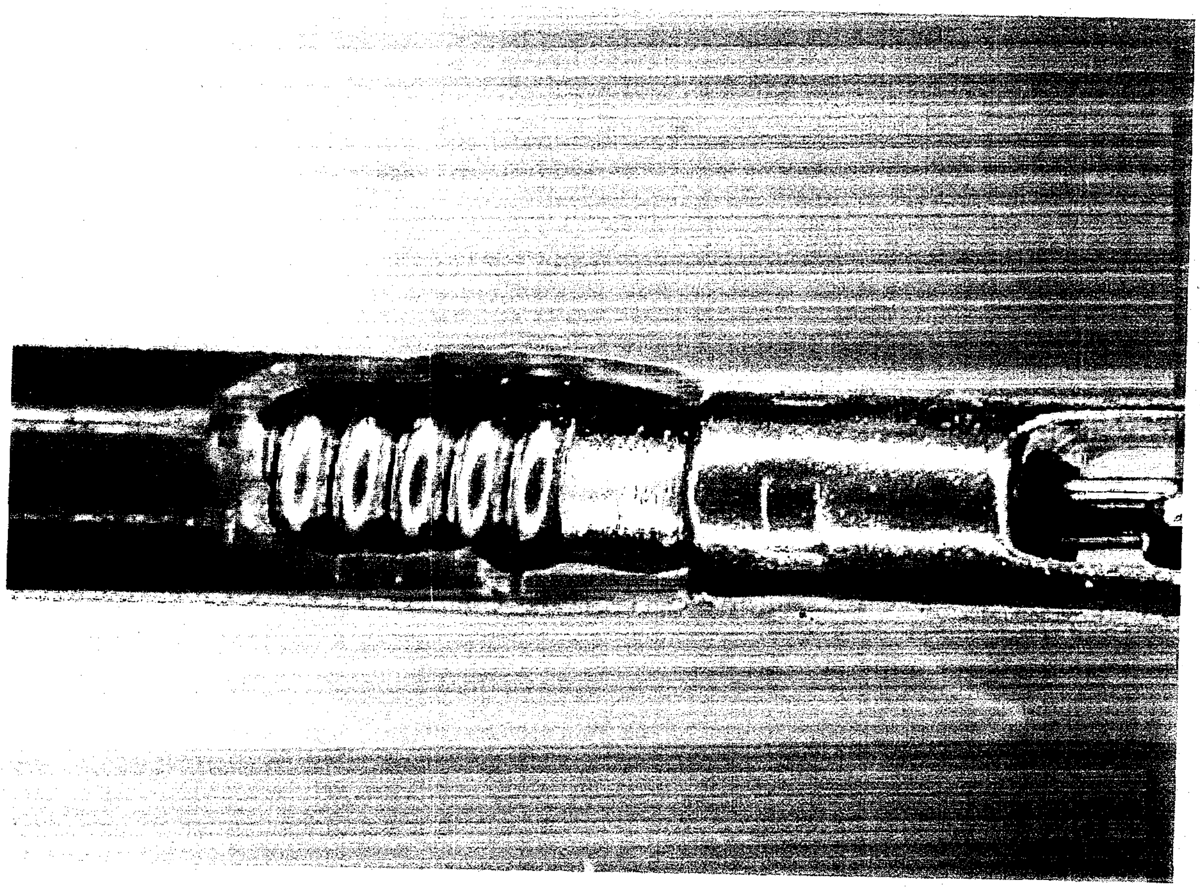
Single use forceps showing inner sheath around wire assembly.
Reusable devices do not have this sheath.

6



Reusable forceps showing welded coil connection and lack of sheath covering.

7



Single use forceps showing crimp design (no weld) and plastic sheath covering.

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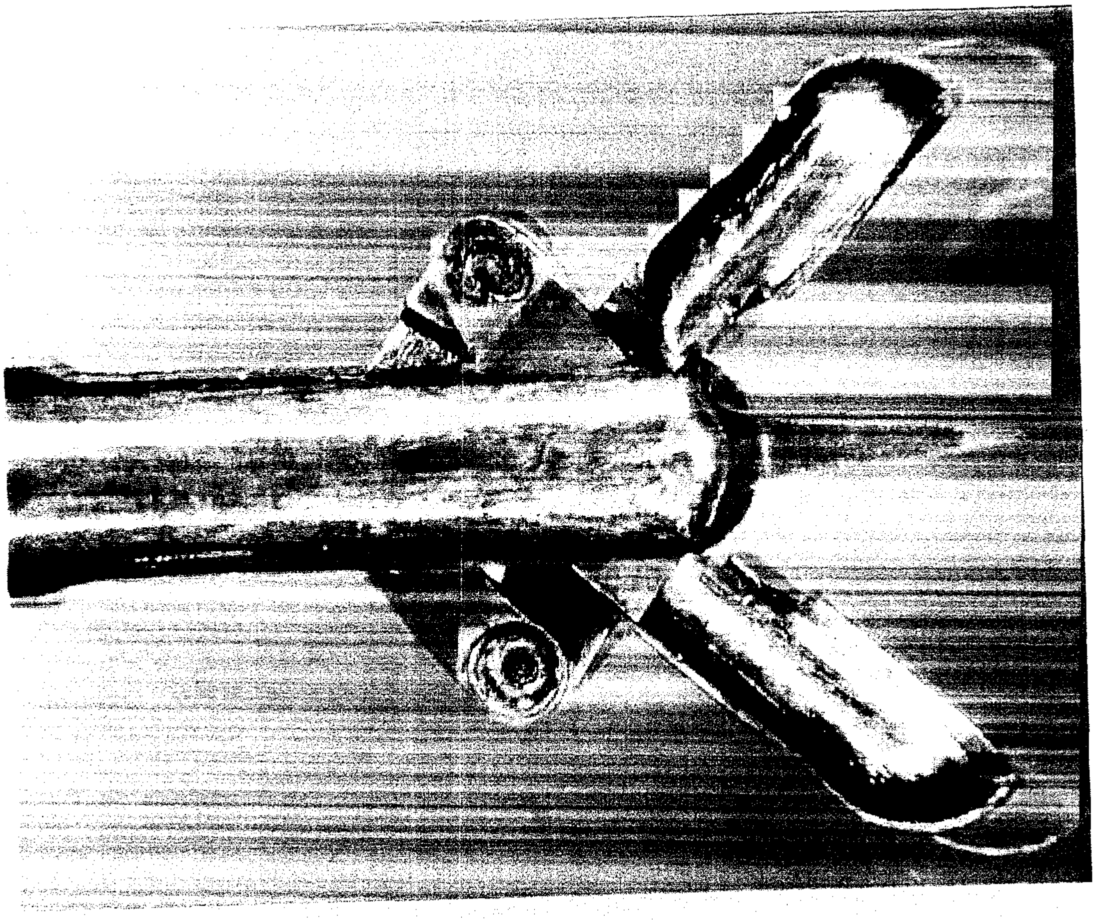

Reusable forceps showing smooth cutting edge and welded joints.

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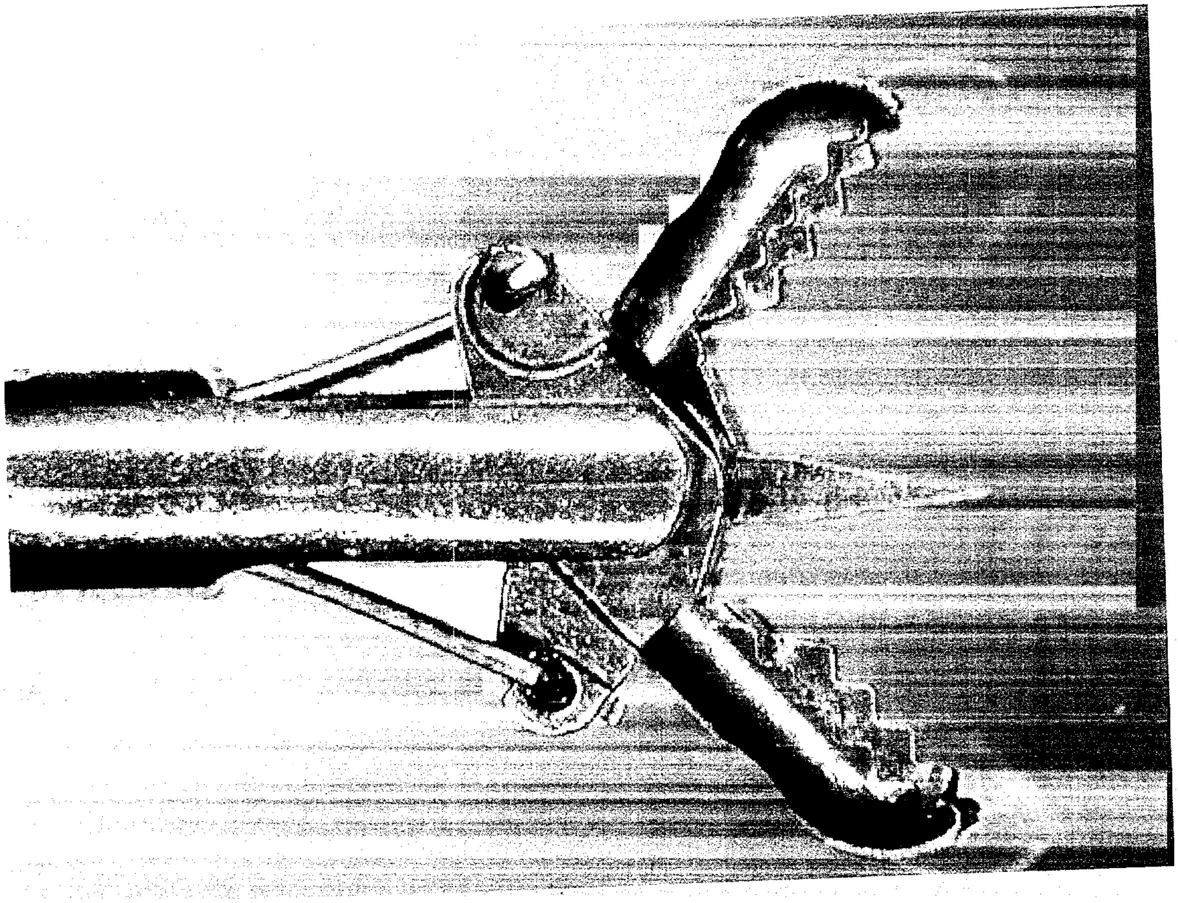

Single use forceps showing micromesh teeth and crimped joint design.

10

FOR HEART PATIENTS, A DEADLY SCARE SCORES UNDERGO ROUTINE PROCEDURE SINCE DEATHS NOV. 11, BUT QUESTIONS LINGER IN CATHETER LAB

Heart patients in the metro area aren't shying away from a routine cardiac catheterization procedure that mysteriously led to two deaths last week at University Hospital.

Since the deaths on Nov. 11, dozens of patients in nearly every other major local hospital have had catheterizations to diagnose coronary artery disease and monitor heart-muscle function.

It's not known whether the equipment **used** at University was responsible for introducing a killer bacterial byproduct called an endotoxin into the bloodstreams of the victims.
Though the deadly disease was restricted to University's second- floor cardiac-**catheter** lab, area hospitals use similar equipment, supplied by the same large medical-supply companies.
Indeed, the only concern expressed about catheterization procedures came from one official who acknowledged that virtually all of the facilities in the metro area could have been exposed to the same tainted equipment.
"There's concern that it's coming from something that, potentially, everyone may be using," said the official, who requested anonymity. "We all get the same products. But we have never had any problems."
Still, hospital officials maintain that **catheter** labs are safe.
"We've had a couple of patients ask about whether that could happen in our cath lab as well," said Beth Forsyth, director of cardiovascular services at Denver's St. Joseph Hospital, where about 3,000 of the procedures are done each year. "We've assured them that everything is cleaned and that there is no problem here."
Most Denver-area hospitals perform heart catheterizations, a sophisticated, painless and increasingly common procedure that usually takes less than an hour.
It usually involves placing thin **catheters** into the femoral artery, located in the groin, and feeding the pencil-thin tubing into the coronary artery. A dye is injected and the inside of the heart can be viewed on a monitor.
"It's a very safe procedure," said Pam Miller, clinical coordinator for Provenant Health Partners, which operates St. Anthony Central and St. Anthony North hospitals.
How the endotoxin got into the supposedly **sterile** environment of University Hospital's **catheter** lab may never be known, said Dr. Tyler Curiel, director of the infection-control program there.
There are only a half-dozen or so ways it could have been introduced, he said - through air ducts, the ceiling, hospital personnel, medicine and the equipment. All medical supplies on hand in the lab at University have been discarded as a preventive measure.
Traces of endotoxin were discovered in one of the flush buckets ***used*** to rinse **catheters.**

MICHAEL ROMANO; ROCKY MOUNTAIN NEWS MEDICAL WRITER, FOR HEART PATIENTS, A DEADLY SCARE SCORES UNDERGO ROUTINE PROCEDURE SINCE